SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				16	Man	29	JAN	2018	

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

LITE TAKYKARD (Tachycardia) - Okänd
Protocol relatedness:
As per reporter:
As per company:

KRÄKTS (Vomited) - Okänd
Protocol relatedness:

Cont...

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Propavan(propiomazine maleate, propiomazine)(propiomazine maleate,
2) sertraline(Sertraline)(Sertraline)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) 500-1000 mg 2) (500 Milligram)	1) Per oral 2) Per oral	☐ YES ☐ NO ☐ NA
17 INDICATIONS FOR USE 1) 2)		
18 THERAPY DATES(From/To) 1) 29/JAN/2018 2) 29/JAN/2018	19 THERAPY DURATION 1) 2)	

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER

MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO 2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER 29/MAY/2019

24d REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT 24/JUN/2021

25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	29/Jan/2018
Seq No	:	2
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	29/Jan/2018
Seq No	:	3
Reaction	:	LITE TAKYKARD (Tachycardia)
Start Date	:	29/Jan/2018
Seq No	:	4
Reaction	:	KRÄKTS (Vomited)
Start Date	:	29/Jan/2018
Seq No	:	5
Reaction	:	TRÖTT (Tiredness)
Start Date	:	29/Jan/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

TRÖTT (Tiredness) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 16-årig pojke, vikt 80-90 kg.
Rapporterat misstänkt läkemedel var Propavan (propiomazine), sertraline. Intag kl 13.30.
Rapporterat som avsiktlig överdosering, avsiktlig självdestruktiv handling. Vid kl 16.15 beskrivs att pojken är stabil, lite takykard (100 i puls), "tryck rel normalt 130/90", trött "men helt med". Pojken hade fått kol i ambulansen, "men ganska sent, nog kräkts upp allt kol".
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Propavan(propiomazine maleate, propiomazine)(propiomazine maleate, propiomazine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 29/JAN/2018 - 29/JAN/2018
Seq No	:	2
Drug	:	sertraline(Sertraline)(Sertraline)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 29/JAN/2018 - 29/JAN/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				17	Kvinna	31	JAN	2019	

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

SLUDDRIG (Slurred speech) - Okänd
Protocol relatedness:
As per reporter:
As per company:

SOMNOLENT (Somnolence) - Okänd
Protocol relatedness:

Cont...

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Propavan(propiomazine maleate, propiomazine)(propiomazine maleate,
2) sertraline(Sertraline)(Sertraline)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) (125 Milligram) 2) (75 Milligram)	1) Per oral 2) Per oral	☐ YES ☐ NO ☐ NA
17 INDICATIONS FOR USE 1) 2)		
18 THERAPY DATES(From/To) 1) 31/JAN/2019 2) 31/JAN/2019	19 THERAPY DURATION 1) 2)	

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER

MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO 2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER 29/MAY/2019

24d REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT 24/JUN/2021

25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	31/Jan/2019
Seq No	:	2
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	31/Jan/2019
Seq No	:	3
Reaction	:	SLUDDRIG (Slurred speech)
Start Date	:	31/Jan/2019
Seq No	:	4
Reaction	:	SOMNOLENT (Somnolence)
Start Date	:	31/Jan/2019

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 17-årig flicka.
Rapporterat misstänkt läkemedel var Propavan (propiomazine), sertraline. Intag "imorse", "kanske kl 8?". Det står att flickan använder medicinerna dagligen.
Rapporterat som avsiktlig överdosering, avsiktlig självdestruktiv handling. Det står även "suicidsyfte?". Vid kl 12.30 beskrivs att flickan är "klart påverkad", sluddrig, och lätt somnolent, "vill sova".
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Propavan(propiomazine maleate, propiomazine)(propiomazine maleate, propiomazine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 31/JAN/2019 - 31/JAN/2019
Seq No	:	2
Drug	:	sertraline(Sertraline)(Sertraline)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 31/JAN/2019 - 31/JAN/2019

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				19	Man	01	JUL	2018	

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

FÖRVIRRAD (Confused) - Okänd
Protocol relatedness:
As per reporter:
As per company:

MEDVETSLÖS (Unconscious) - Okänd
Protocol relatedness:

Cont...

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) promethazine(Promethazine)(Promethaz-
2) melatonin(Melatonin)(Melatonin)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) 2)	1) Per oral 2) Per oral	☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 01/JUL/2018 2) 01/JUL/2018	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER
29/MAY/2019

24d REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
24/JUN/2021

25a REPORT TYPE
☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	01/Jul/2018
Seq No	:	2
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	01/Jul/2018
Seq No	:	3
Reaction	:	FÖRVIRRAD (Confused)
Start Date	:	01/Jul/2018
Seq No	:	4
Reaction	:	MEDVETSLÖS (Unconscious)
Start Date	:	01/Jul/2018
Seq No	:	5
Reaction	:	ONT I BENEN (Pains in legs)
Start Date	:	01/Jul/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

ONT I BENEN (Pains in legs) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 19-årig man. Den medicinska historien inkluderade asperger.
Rapporterat misstänkt läkemedel var Alvedon (paracetamol), Paraflex (chlorzoxazone), citalopram, melatonin, naproxen, promethazine. 1 näve av olika läkemedel, oklart hur mycket. Rapporterat som avsiktlig överdosering, avsiktlig självdestruktiv handling, förvirrad, medvetslös, ont i benen. "Kom in medvetandesänkt, nu ua." Hittar inget avvikande. ASAT 1,2 (ref S-ASAT 0,25-0,75 µkat/L). S-paracetamol ej påvisbart.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Ref. enligt NORIP/Equalis.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	promethazine(Promethazine)(Promethazine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 01/JUL/2018 - 01/JUL/2018
Seq No	:	2
Drug	:	melatonin(Melatonin)(Melatonin)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 01/JUL/2018 - 01/JUL/2018
Seq No	:	3
Drug	:	citalopram(Citalopram)(Citalopram)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 01/JUL/2018 - 01/JUL/2018
Seq No	:	4
Drug	:	naproxen(Naproxen)(Naproxen)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 01/JUL/2018 - 01/JUL/2018
Seq No	:	5
Drug	:	Paraflex(chlorzoxazone)(chlorzoxazone)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 01/JUL/2018 - 01/JUL/2018
Seq No	:	6
Drug	:	Alvedon(paracetamol)(paracetamol)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 01/JUL/2018 - 01/JUL/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4 -6 REACTION ONSET DA	MO	YR	8 -12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				15	Kvinna		DEC	2018	

7 +13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

TEMP 38,3 (Temperature elevation) - Okänd
Protocol relatedness:
As per reporter:
As per company:

STORA PUPILLER (Dilated pupils) - Okänd
Protocol relatedness:

Cont...

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine
2) sertraline(Sertraline)(Sertraline)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) 2) (2 Gram)	1) Per oral 2) Per oral	☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 14/DEC/2018 2) 14/DEC/2018	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER	24d REPORT SOURCE
29/MAY/2019	☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER
DATE OF THIS REPORT: 24/JUN/2021	25a REPORT TYPE: ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	14/Dec/2018
Seq No	:	2
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	14/Dec/2018
Seq No	:	3
Reaction	:	TEMP 38,3 (Temperature elevation)
Start Date	:	14/Dec/2018
Stop Date	:	15/Dec/2018
Duration	:	1 Dagar
Seq No	:	4
Reaction	:	STORA PUPILLER (Dilated pupils)
Start Date	:	14/Dec/2018
Seq No	:	5
Reaction	:	HYPERREFLEXI (Hyperreflexia)
Start Date	:	/Dec/2018
Seq No	:	6
Reaction	:	PRATAR OSAMMANHÄNGANDE (Incoherent)
Start Date	:	15/Dec/2018
Seq No	:	7
Reaction	:	HALLUCINOS, SÄGER KONSTIGA SAKER (Hallucination)
Start Date	:	15/Dec/2018
Seq No	:	8
Reaction	:	DESORIENTERAD (Disorientation)
Start Date	:	15/Dec/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

HYPERREFLEXI (Hyperreflexia) - Okänd
Protocol relatedness:
As per reporter:
As per company:

PRATAR OSAMMANHÄNGANDE (Incoherent) - Okänd
Protocol relatedness:
As per reporter:
As per company:

HALLUCINOS, SÄGER KONSTIGA SAKER (Hallucination) - Okänd
Protocol relatedness:
As per reporter:
As per company:

DESORIENTERAD (Disorientation) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 15-årig flicka.
Rapporterat misstänkt läkemedel var Alvedon (paracetamol), Lergigan (promethazine), sertraline. Intagen dos a
v respektive läkemedel var 2 g sertralin, 15 g Alvedon samt lergigan där den intagna dosen anges som både so
m 400mg och 2 g således oklart hur stor dosen egentligen var.

Rapporterat som avsiktlig självdestruktiv handling, avsiktlig överdosering, temp 38,3, stora pupiller, hyperr
eflexi, pratar osammanhängande, hallucinos, säger konstiga saker, desorienterad.
Enligt rapport initialt temp på 38,3 och pupiller stora men ljusreagerande, ca 9 timmar efter intag puls på 1
25 (som vid inkomst var 90), har börjat hallucinera, pratar osammanhängande, desorienterad.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 14/DEC/2018 - 14/DEC/2018
Seq No	:	2
Drug	:	sertraline(Sertraline)(Sertraline)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 14/DEC/2018 - 14/DEC/2018
Seq No	:	3
Drug	:	Alvedon(paracetamol)(paracetamol)
Daily Dose	:	1) (15 Gram)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Route of Admin : 1) Per oral
Therapy Dates/Duration : 1) 14/DEC/2018 - 14/DEC/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	2 DATE OF BIRTH MO	2 DATE OF BIRTH YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	4-6 REACTION ONSET MO	4-6 REACTION ONSET YR
	SVERIGE				18	Man	01	MAR	2018

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

MEDVETANDESÄNKT (Consciousness decreased) - Okänd
Protocol relatedness:
As per reporter:
As per company:

KRÄKTS (Vomited) - Okänd
Protocol relatedness:

Cont...

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine
2) mirtazapine(Mirtazapine)(Mirtazapine)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION
1) "20-30 st á 25- 2) "45 mg, max 20 -	1) Per oral 2) Per oral

21 DID EVENT REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 01/MAR/2018 2) 01/MAR/2018	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER
29/MAY/2019

24d REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
24/JUN/2021

25a REPORT TYPE
☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	01/Mar/2018
Seq No	:	2
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	01/Mar/2018
Seq No	:	3
Reaction	:	MEDVETANDESÄNKT (Consciousness decreased)
Start Date	:	01/Mar/2018
Seq No	:	4
Reaction	:	KRÄKTS (Vomited)
Start Date	:	01/Mar/2018
Seq No	:	5
Reaction	:	TRÖTT (Tiredness)
Start Date	:	01/Mar/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

TRÖTT (Tiredness) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 18-årig man.
Rapporterat misstänkt läkemedel var Lergigan (promethazine), mirtazapine. Rapporterat som avsiktlig överdose
ring, avsiktlig självdestruktiv handling,
medvetandesänkt, kräkts, trött.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Daily Dose	:	1) "20-30 st á 25 mg"
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 01/MAR/2018 - 01/MAR/2018
Seq No	:	2
Drug	:	mirtazapine(Mirtazapine)(Mirtazapine)
Daily Dose	:	1) "45 mg, max 20 st"
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 01/MAR/2018 - 01/MAR/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				14	Kvinna	28	NOV	2018	

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

FÖRVIRRAD (Confused) - Okänd
Protocol relatedness:
As per reporter:
As per company:

PLOCKIG (Motor restlessness) - Okänd
Protocol relatedness:

Cont...

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan mite(promethazine, promethazine
2) fluoxetine(Fluoxetine)(Fluoxetine)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) 2)	1) Per oral 2) Per oral	☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 28/NOV/2018 2) 28/NOV/2018	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER

MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO 2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER 29/MAY/2019

24d REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT 24/JUN/2021

25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	28/Nov/2018
Seq No	:	2
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	28/Nov/2018
Seq No	:	3
Reaction	:	FÖRVIRRAD (Confused)
Start Date	:	28/Nov/2018
Seq No	:	4
Reaction	:	PLOCKIG (Motor restlessness)
Start Date	:	28/Nov/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 14-årig flicka.
Rapporterat misstänkt läkemedel var Lergigan mite (promethazine), fluoxetine i oklara mängder "värsta fall 300 mg lergigan" "kanske 600 mg i värsta fall". Rapporterat som avsiktlig överdosering, avsiktlig självdestruktiv handling, förvirrad, plockig. Stabila vitalparametrar.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan mite(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 28/NOV/2018 - 28/NOV/2018
Seq No	:	2
Drug	:	fluoxetine(Fluoxetine)(Fluoxetine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 28/NOV/2018 - 28/NOV/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR
	SVERIGE				18	Kvinna	15	MAY	2018

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

7 +13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 18-årig kvinna.
Rapporterat misstänkt läkemedel var Propavan (propiomazine), sertraline ("30 se

Cont...

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Propavan(propiomazine maleate, propiomazine)(propiomazine maleate,
2) sertraline(Sertraline)(Sertraline)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) (400 Milligram) 2) "30 sertralin o-	1) Per oral 2) Per oral	☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 15/MAY/2018 2) 15/MAY/2018	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY
No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER	24d REPORT SOURCE
29/MAY/2019	☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER
DATE OF THIS REPORT 24/JUN/2021	25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	15/May/2018
Seq No	:	2
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	15/May/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

rtralin okänd styrka, 50 mg zoloft"). Intag "antaglige ganska nyligen".
Rapporterat som avsiktlig överdosering, avsiktlig självdestruktiv handling.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Propavan(propiomazine maleate, propiomazine)(propiomazine maleate, propiomazine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 15/MAY/2018 - 15/MAY/2018
Seq No	:	2
Drug	:	sertraline(Sertraline)(Sertraline)
Daily Dose	:	1) "30 sertralin okänd styrka, 50 mg zoloft"
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 15/MAY/2018 - 15/MAY/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	2 DATE OF BIRTH MO	2 DATE OF BIRTH YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	4-6 REACTION ONSET MO	4-6 REACTION ONSET YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				16	Kvinna	09	OCT	2018	

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

ÅNGESTFYLLD (Anxiety) - Okänd
Protocol relatedness:
As per reporter:
As per company:

TAKYKARDI (Tachycardia) - Okänd
Protocol relatedness:

Cont...

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine
2) Ipren(ibuprofen, Ibuprofen DC 85)(ibuprofen, Ibuprofen DC 85)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE
1) *15 st lergigan- 2) (400 Milligram)

16 ROUTE OF ADMINISTRATION
1) Per oral 2) Per oral

21 DID EVENT REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)
1) 09/OCT/2018 2) 09/OCT/2018

19 THERAPY DURATION
1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER
29/MAY/2019

24d REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
24/JUN/2021

25a REPORT TYPE
☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	09/Oct/2018
Seq No	:	2
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	09/Oct/2018
Seq No	:	3
Reaction	:	ÅNGESTFYLLD (Anxiety)
Start Date	:	09/Oct/2018
Seq No	:	4
Reaction	:	TAKYKARDI (Tachycardia)
Start Date	:	09/Oct/2018
Seq No	:	5
Reaction	:	HJÄRTKLAPPNING (Heart pounding)
Start Date	:	09/Oct/2018
Seq No	:	6
Reaction	:	MÅR ILLA (Nausea)
Start Date	:	09/Oct/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

HJÄRTKLAPPNING (Heart pounding) - Okänd
Protocol relatedness:
As per reporter:
As per company:

MÅR ILLA (Nausea) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 16-årig flicka.

Rapporterat misstänkt läkemedel var 400 mg Ipren (ibuprofen), 15 st Lergigan (promethazine), 2 st Ritalin (me
thylphenidate), 3 st Theralen (alimemazine). Vid ankomst till sjukhus en timme efter intaget rapporterat som
avsiktlig självdestruktiv handling, avsiktlig överdosering. Flickan är ångestfylld, takykardi 113, hjärtkl
appning och mår illa. Adekvat, stabil, RLS 1.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Daily Dose	:	1) "15 st lergigan 25 och 5 mg"
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 09/OCT/2018 - 09/OCT/2018
Seq No	:	2
Drug	:	Ipren(ibuprofen, Ibuprofen DC 85)(ibuprofen, Ibuprofen DC 85)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 09/OCT/2018 - 09/OCT/2018
Seq No	:	3
Drug	:	Ritalin(methylphenidate hydrochloride, methylphenidate)(methylphenidate hydrochloride, methylphenidate)
Daily Dose	:	1) 2 st
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 09/OCT/2018 - 09/OCT/2018
Seq No	:	4
Drug	:	Theralen(alimemazine, alimemazine hemitartrate)(alimemazine, alimemazine hemitartrate)
Daily Dose	:	1) 3 st
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 09/OCT/2018 - 09/OCT/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted] (0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				17	Man	01	OCT	2018	

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 17-årig pojke.
Rapporterat misstänkt läkemedel var Lergigan (promethazine), sertraline. Rappor

Cont...

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine
2) sertraline(Sertraline)(Sertraline)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) "ca 500 mg" 2)	1) Per oral 2) Per oral	☐ YES ☐ NO ☐ NA
17 INDICATIONS FOR USE 1)	2)	
18 THERAPY DATES(From/To) 1) 01/OCT/2018 2) 01/OCT/2018	19 THERAPY DURATION 1) 2)	

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted] (0)

24c DATE RECEIVED BY MANUFACTURER
29/MAY/2019

24d REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
24/JUN/2021

25a REPORT TYPE
☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed SMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	01/Oct/2018
Seq No	:	2
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	01/Oct/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

terat som avsiktlig överdosering, avsiktlig självdestruktiv handling.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 01/OCT/2018 - 01/OCT/2018
Seq No	:	2
Drug	:	sertraline(Sertraline)(Sertraline)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 01/OCT/2018 - 01/OCT/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	2 DATE OF BIRTH MO	2 DATE OF BIRTH YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	4-6 REACTION ONSET MO	4-6 REACTION ONSET YR
	SVERIGE				18	Kvinna	11	APR	2018

7 +13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

SKAKIG (Shakiness) - Okänd
Protocol relatedness:
As per reporter:
As per company:

TAKYKARD (Tachycardia) - Okänd
Protocol relatedness:

Cont...

8 -12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine
2) Attentin(dexamfetamine sulfate, dexamfetamine)(dexamfetamine sulfate,

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE
1) 25 mg, 30 styck- 2) 5 mg, 30 stycken

16 ROUTE OF ADMINISTRATION
1) Per oral 2) Per oral

21 DID EVENT REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)
1) 11/APR/2018 2) 11/APR/2018

19 THERAPY DURATION
1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER

MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER
29/MAY/2019

24d REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
24/JUN/2021

25a REPORT TYPE
☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	11/Apr/2018
Seq No	:	2
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	11/Apr/2018
Seq No	:	3
Reaction	:	SKAKIG (Shakiness)
Start Date	:	11/Apr/2018
Seq No	:	4
Reaction	:	TAKYKARD (Tachycardia)
Start Date	:	11/Apr/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 18-årig kvinna.
Rapporterat misstänkt läkemedel var Attentin (dexamfetamine) 5mg 30 stycken, Lergigan (promethazine) 25 mg 30 stycken.
Rapporterat som avsiktlig överdosering, avsiktlig självdestruktiv handling. Vid första samtalet till Giftinf ormationscentralen var kvinnan vaken, talbar och skakig.
På sjukhuset 1,5 timme efter intag är kvinnan "stabil" och takykard. Har fått kol i ambulansen.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Daily Dose	:	1) 25 mg, 30 stycken lergigan
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 11/APR/2018 - 11/APR/2018
Seq No	:	2
Drug	:	Attentin(dexamfetamine sulfate, dexamfetamine)(dexamfetamine sulfate, dexamfetamine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 11/APR/2018 - 11/APR/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				17	Kvinna	20	JUL	2019	

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

MISSBRUK, BERUSNINGSSYFTE (Drug abuse) - Okänd
Protocol relatedness:
As per reporter:
As per company:

TRÖTT (Tiredness) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

Cont...

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Propavan(propiomazine maleate, propiomazine)(propiomazine maleate,
2) melatonin(Melatonin)(Melatonin)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE
1) (50 Milligram) 2) (15 Milligram)

16 ROUTE OF ADMINISTRATION
1) Nasal 2) Nasal

21 DID EVENT REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)
1) 20/JUL/2019 2) 20/JUL/2019

19 THERAPY DURATION
1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER
03/AUG/2019

24d REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
24/JUN/2021

25a REPORT TYPE
☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	20/Jul/2019
Seq No	:	2
Reaction	:	MISSBRUK, BERUSNINGSSYFTE (Drug abuse)
Start Date	:	20/Jul/2019
Seq No	:	3
Reaction	:	TRÖTT (Tiredness)
Start Date	:	21/Jul/2019

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 17-årig flicka.
Rapporterat misstänkt läkemedel var Propavan (propiomazine), melatonin, sertraline. Flickan krossade dem vid 23-tiden och därefter tagit/sniffat "melatonin 5 st 3 mg, 2 st propavan 25 mg, 1 sertraline 50 mg".

Rapporterat som avsiktlig överdosering, missbruk, berusningssyfte. Flickan är trött drygt två timmar senare . Intog vid 21-tiden även sina vanliga doser. Framkommer ej mer information om det.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Propavan(propiomazine maleate, propiomazine)(propiomazine maleate, propiomazine)
Route of Admin	:	1) Nasal
Therapy Dates/Duration	:	1) 20/JUL/2019 - 20/JUL/2019
Seq No	:	2
Drug	:	melatonin(Melatonin)(Melatonin)
Route of Admin	:	1) Nasal
Therapy Dates/Duration	:	1) 20/JUL/2019 - 20/JUL/2019
Seq No	:	3
Drug	:	sertraline(Sertraline)(Sertraline)
Daily Dose	:	1) (50 Milligram)
Route of Admin	:	1) Nasal
Therapy Dates/Duration	:	1) 20/JUL/2019 - 20/JUL/2019

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				15	Man	25	MAR	2019	

7 +13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

ÖVERDOSERING AV MISSTAG (Drug overdose accidental) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

Cont...

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine
2) sertraline(Sertraline)(Sertraline)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) (150 Milligram) 2) 300-375 mg	1) Per oral 2) Per oral	☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 25/MAR/2019 2) 25/MAR/2019	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER	24d REPORT SOURCE
29/MAY/2019	☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER
DATE OF THIS REPORT 24/JUN/2021	25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	25/Mar/2019
Seq No	:	2
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	25/Mar/2019
Seq No	:	3
Reaction	:	ÖVERDOSERING AV MISSTAG (Drug overdose accidental)
Start Date	:	25/Mar/2019

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 15-årig pojke.
Rapporterat misstänkt läkemedel var 120-180 mg Elvanse (lisdexamfetamine), 6x25 mg Lergigan (promethazine) oc
h 300-375 mg sertraline. "kan ha tagit theralen och melatonin också". Rapporterat både som avsiktlig överdos
ering, avsiktlig självdestruktiv handling och överdosering av misstag, det står att pojken fick alla sina me
diciner på en gång. Inga symtom finns rapporterade.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 25/MAR/2019 - 25/MAR/2019
Seq No	:	2
Drug	:	sertraline(Sertraline)(Sertraline)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 25/MAR/2019 - 25/MAR/2019
Seq No	:	3
Drug	:	Elvanse(lisdexamfetamine dimesilate, lisdexamfetamine, dexamfetamine)(lisdexamfetamine dimesilate, lisdexamfetamine, dexamfetamine)
Daily Dose	:	1) 120-180 mg
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 25/MAR/2019 - 25/MAR/2019

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted] (0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR
	SVERIGE				16	Kvinna	21	NOV	2018

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 16-årig flicka.
Rapporterat misstänkt läkemedel och intagen dos var, okänd dos Oxascand (oxaze

Cont...

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Propavan(propiomazine maleate, propiomazine)(propiomazine maleate,

2) Theralen(alimemazine, alimemazine hemitartrate)(alimemazine,

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE
1) (375 Milligram) 2) (500 Milligram)

16 ROUTE OF ADMINISTRATION
1) Per oral 2) Per oral

21 DID EVENT REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)
1) 21/NOV/2018 2) 21/NOV/2018

19 THERAPY DURATION
1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted] (0)

24c DATE RECEIVED BY MANUFACTURER
29/MAY/2019

24d REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
24/JUN/2021

25a REPORT TYPE
☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	21/Nov/2018
Seq No	:	2
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	21/Nov/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

pam), 375 mg Propavan (propiomazine), 500 mg Theralen (alimemazine), okänd dos mirtazapine. Rapporterat som av siktlig självdestruktiv handling, avsiktlig överdosering.
RLS 1, fått kol.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Propavan(propiomazine maleate, propiomazine)(propiomazine maleate, propiomazine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 21/NOV/2018 - 21/NOV/2018
Seq No	:	2
Drug	:	Theralen(alimemazine, alimemazine hemitartrate)(alimemazine, alimemazine hemitartrate)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 21/NOV/2018 - 21/NOV/2018
Seq No	:	3
Drug	:	Oxascand(oxazepam)(oxazepam)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 21/NOV/2018 - 21/NOV/2018
Seq No	:	4
Drug	:	mirtazapine(Mirtazapine)(Mirtazapine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 21/NOV/2018 - 21/NOV/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				16	Kvinna	16	JAN	2018	

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

GRAVT MEDVETANDESÄNKT (Consciousness decreased) - Okänd
Protocol relatedness:
As per reporter:
As per company:

KRÅKTS (Vomited) - Okänd
Protocol relatedness:

Cont...

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Propavan(propiomazine maleate, propiomazine)(propiomazine maleate,

2) Ibumetin(ibuprofen)(ibuprofen)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION
1) 20 st á 25 mg - 2) 44 st á 400 mg-	1) Per oral 2)

21 DID EVENT REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 16/JAN/2018 2) 16/JAN/2018	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER
29/MAY/2019

24d REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
24/JUN/2021

25a REPORT TYPE
☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	16/Jan/2018
Seq No	:	2
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	16/Jan/2018
Seq No	:	3
Reaction	:	GRAVT MEDVETANDESÄNKT (Consciousness decreased)
Start Date	:	16/Jan/2018
Seq No	:	4
Reaction	:	KRÄKTS (Vomited)
Start Date	:	16/Jan/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 16-årig flicka.
Rapporterat misstänkt läkemedel var Ibumetin (ibuprofen), Propavan (propiomazine), fluoxetine, paracetamol, q
uetiapine, sertraline. Rapporterat som avsiktlig
självdestruktiv handling, avsiktlig överdosering. Samtidigt alkoholintag.
Intag kl 15:30-18. Läkare på sjukhus kontaktar Giftinformationscentralen 18:54. Det framkommer att flickan
är "gravt medvetandesänkt" samt "stabil cirk".
Flickan har kräks flera gånger, oklart när.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Propavan(propiomazine maleate, propiomazine)(propiomazine maleate, propiomazine)
Daily Dose	:	1) 20 st á 25 mg (500 Milligram)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 16/JAN/2018 - 16/JAN/2018
Seq No	:	2
Drug	:	Ibumetin(ibuprofen)(ibuprofen)
Daily Dose	:	1) 44 st á 400 mg (17600 Milligram)
Therapy Dates/Duration	:	1) 16/JAN/2018 - 16/JAN/2018
Seq No	:	3
Drug	:	paracetamol(Paracetamol)(Paracetamol)
Daily Dose	:	1) 10 st á 500 mg (5000 Milligram)
Therapy Dates/Duration	:	1) 16/JAN/2018 - 16/JAN/2018
Seq No	:	4
Drug	:	quetiapine(Quetiapine)(Quetiapine)
Daily Dose	:	1) 10 st á 25 mg (250 Milligram)
Therapy Dates/Duration	:	1) 16/JAN/2018 - 16/JAN/2018
Seq No	:	5
Drug	:	sertraline(Sertraline)(Sertraline)
Daily Dose	:	1) 10 st á 100 mg (1000 Milligram)
Therapy Dates/Duration	:	1) 16/JAN/2018 - 16/JAN/2018
Seq No	:	6
Drug	:	fluoxetine(Fluoxetine)(Fluoxetine)
Daily Dose	:	1) 5-6 st
Therapy Dates/Duration	:	1) 16/JAN/2018 - 16/JAN/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				14	Kvinna		JUN	2018	

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

SLUDDRIG (Slurred speech) - Okänd
Protocol relatedness:
As per reporter:
As per company:

OSAMMANHÅNGANDE (Disorganised speech) - Okänd
Protocol relatedness:

Cont...

☐ PATIENT DIED
☐ LIFE THREATENING
☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
☐ CONGENITAL ANOMALY
☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Propavan(propiomazine maleate, propiomazine)(propiomazine maleate,
2) melatonin(Melatonin)(Melatonin)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) 15 st 2)	1) Per oral 2) Per oral	☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 11/JUN/2018 2) 11/JUN/2018	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER	24d REPORT SOURCE
29/MAY/2019	☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER
DATE OF THIS REPORT 24/JUN/2021	25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	11/Jun/2018
Seq No	:	2
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	11/Jun/2018
Seq No	:	3
Reaction	:	SLUDDRIG (Slurred speech)
Start Date	:	11/Jun/2018
Seq No	:	4
Reaction	:	OSAMMANHÅNGANDE (Disorganised speech)
Start Date	:	11/Jun/2018
Seq No	:	5
Reaction	:	HALLUCINERA (Hallucination)
Start Date	:	/Jun/2018
Seq No	:	6
Reaction	:	OROLIG (Anxiety)
Start Date	:	/Jun/2018
Seq No	:	7
Reaction	:	INTE KONTAKTBAR (Unresponsive to stimuli)
Start Date	:	/Jun/2018
Seq No	:	8
Reaction	:	TAKYKARD (Tachycardia)
Start Date	:	/Jun/2018
Seq No	:	9
Reaction	:	KRÅKTS (Vomited)
Start Date	:	11/Jun/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

HALLUCINERA (Hallucination) - Okänd
Protocol relatedness:
As per reporter:
As per company:

OROLIG (Anxiety) - Okänd
Protocol relatedness:
As per reporter:
As per company:

INTE KONTAKTBAR (Unresponsive to stimuli) - Okänd
Protocol relatedness:
As per reporter:
As per company:

TAKYKARD (Tachycardia) - Okänd
Protocol relatedness:
As per reporter:
As per company:

KRÅKTS (Vomited) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 14-årig flicka.
Rapporterat misstänkt läkemedel var Propavan (propiomazine), fluoxetine, melatonin. Intag kl 22.30.
Rapporterat som avsiktlig överdosering, avsiktlig självdestruktiv handling. Hade kräkts 10 minuter efter int
ag och blev "direkt" efter intag sluddrig och osammanhängande. Hallucinerade "efter". Vid kl 01 beskrivs att f
lickan var tung i kroppen, orolig, inte kontaktbar, "svarar inte alls, syresätter sig bra" samt är takykard.

Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Propavan(propiomazine maleate, propiomazine)(propiomazine maleate, propiomazine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 11/JUN/2018 - 11/JUN/2018
Seq No	:	2
Drug	:	melatonin(Melatonin)(Melatonin)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 11/JUN/2018 - 11/JUN/2018

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Seq No	:	3
Drug	:	fluoxetine(Fluoxetine)(Fluoxetine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 11/JUN/2018 - 11/JUN/2018

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	30/Jul/2019
Seq No	:	2
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	30/Jul/2019
Seq No	:	3
Reaction	:	LITE TRÖTT (Tiredness)
Start Date	:	30/Jul/2019
Seq No	:	4
Reaction	:	SLÖ (Lethargy)
Start Date	:	30/Jul/2019

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 12-årig flicka.
Rapporterat misstänkt läkemedel var Atarax (hydroxyzine), Lergigan (promethazine), Theralen (alimemazine), fl uoxetine, Alvedon (paracetamol). Anges som "oklara mängder och oklara substanser". Tidpunkt för intag oklart (före 16).

Rapporterat som avsiktlig överdosering, avsiktlig självdestruktiv handling. Flickan är vid 17-tiden "helt st abil, lite trött och slö". Vid 18-tiden kommer svar på "s-paracetamol 1139"*. Då kontaktas Giftinformations centralen igen rekommenderar "Nac snarast".
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre
* referens saknas

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 30/JUL/2019 - 30/JUL/2019
Seq No	:	2
Drug	:	Theralen(alimemazine, alimemazine hemitartrate)(alimemazine, alimemazine hemitartrate)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 30/JUL/2019 - 30/JUL/2019
Seq No	:	3
Drug	:	fluoxetine(Fluoxetine)(Fluoxetine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 30/JUL/2019 - 30/JUL/2019
Seq No	:	4
Drug	:	Atarax(hydroxyzine hydrochloride, hydroxyzine)(hydroxyzine hydrochloride, hydroxyzine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 30/JUL/2019 - 30/JUL/2019
Seq No	:	5
Drug	:	Alvedon(paracetamol)(paracetamol)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 30/JUL/2019 - 30/JUL/2019

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				12	Kvinna	30	JUL	2019	

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

LITE TRÖTT (Tiredness) - Okänd
Protocol relatedness:
As per reporter:
As per company:

SLÖ (Lethargy) - Okänd
Protocol relatedness:

Cont...

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine

2) Theralen(alimemazine, alimemazine hemitartrate)(alimemazine,

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE
1) 2)

16 ROUTE OF ADMINISTRATION
1) Per oral 2) Per oral

21 DID EVENT REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)
1) 30/JUL/2019 2) 30/JUL/2019

19 THERAPY DURATION
1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER
03/AUG/2019

24d REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
24/JUN/2021

25a REPORT TYPE
☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR
	SVERIGE				16	Kvinna	12	SEP	2018

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

TRÖGA PUPILLER (Pupillary reaction slow) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

Cont...

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine
2) melatonin(Melatonin)(Melatonin)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION
1) (175 Milligram) 2)	1) Per oral 2) Per oral

21 DID EVENT REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 12/SEP/2018 2) 12/SEP/2018	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER

MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO 2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER 29/MAY/2019

24d REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT 24/JUN/2021

25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	12/Sep/2018
Seq No	:	2
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	12/Sep/2018
Seq No	:	3
Reaction	:	TRÖGA PUPILLER (Pupillary reaction slow)
Start Date	:	12/Sep/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 16-årig flicka.
Rapporterat misstänkt läkemedel var Lergigan (promethazine), melatonin, mirtazapine. Rapporterat som avsiktli
g överdosering, avsiktlig självdestruktiv handling. Cirka 1,5 timme efter intag beskrivs flickan ha tröga pu
piller.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 12/SEP/2018 - 12/SEP/2018
Seq No	:	2
Drug	:	melatonin(Melatonin)(Melatonin)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 12/SEP/2018 - 12/SEP/2018
Seq No	:	3
Drug	:	mirtazapine(Mirtazapine)(Mirtazapine)
Daily Dose	:	1) (15 Milligram)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 12/SEP/2018 - 12/SEP/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				19	Man	04	JUN	2018	

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

MEDVETSLÖS (Unconscious) - Okänd
Protocol relatedness:
As per reporter:
As per company:

MYDRIASIS (Mydriasis) - Okänd
Protocol relatedness:

Cont...

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine
2) fluoxetine(Fluoxetine)(Fluoxetine)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) "oklar mängd" 2) "oklar mängd"	1) Per oral 2) Per oral	☐ YES ☐ NO ☐ NA
17 INDICATIONS FOR USE 1) 2)		
18 THERAPY DATES(From/To) 1) 04/JUN/2018 2) 04/JUN/2018	19 THERAPY DURATION 1) 2)	

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER
29/MAY/2019

24d REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
24/JUN/2021

25a REPORT TYPE
☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	04/Jun/2018
Seq No	:	2
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	04/Jun/2018
Seq No	:	3
Reaction	:	MEDVETSLÖS (Unconscious)
Start Date	:	04/Jun/2018
Seq No	:	4
Reaction	:	MYDRIASIS (Mydriasis)
Start Date	:	04/Jun/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 19-årig man.
Rapporterat misstänkt läkemedel var Lergigan (promethazine), fluoxetine. Rapporterat som avsiktlig självdest
ruktiv handling, avsiktlig överdosering, medvetslös,
mydriasis. Framgår även att mannen "sträckkrampar i armarna" vidare framgår att mannen har "snabb andning"
samt "s-vågor i avledningar".
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 04/JUN/2018 - 04/JUN/2018
Seq No	:	2
Drug	:	fluoxetine(Fluoxetine)(Fluoxetine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 04/JUN/2018 - 04/JUN/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR
	SVERIGE				17	Man	30	MAY	2018

7 +13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

TAKYKARD (Tachycardia) - Okänd
Protocol relatedness:
As per reporter:
As per company:

DYSKINESIER (Dyskinesia) - Okänd
Protocol relatedness:

Cont...

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine

2) Equasym Depot 20 mg Kapsel med modifierad frisättning, hård(Equasy

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) 2)	1) Per oral 2) Per oral	☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 30/MAY/2018 2) 30/MAY/2018	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY
No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER
29/MAY/2019

24d REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
24/JUN/2021

25a REPORT TYPE
☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	30/May/2018
Seq No	:	2
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	30/May/2018
Seq No	:	3
Reaction	:	TAKYKARD (Tachycardia)
Start Date	:	30/May/2018
Seq No	:	4
Reaction	:	DYSKINESIER (Dyskinesia)
Start Date	:	30/May/2018
Seq No	:	5
Reaction	:	FÖRVIRRAD (Confused)
Start Date	:	30/May/2018
Seq No	:	6
Reaction	:	LÄTT ACIDOS (Acidosis)
Start Date	:	30/May/2018
Seq No	:	7
Reaction	:	OROLIG (Anxiety)
Start Date	:	30/May/2018
Seq No	:	8
Reaction	:	HALLUCINATIONER (Hallucinations)
Start Date	:	31/May/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

FÖRVIRRAD (Confused) - Okänd
Protocol relatedness:
As per reporter:
As per company:

LÄTT ACIDOS (Acidosis) - Okänd
Protocol relatedness:
As per reporter:
As per company:

OROLIG (Anxiety) - Okänd
Protocol relatedness:
As per reporter:
As per company:

HALLUCINATIONER (Hallucinations) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 17-årig pojke.
Rapporterat misstänkt läkemedel var Equasym Depot (methylphenidate), Lergigan (promethazine). Rapporterat som avsiktlig överdosering, avsiktlig självdestruktiv handling, takykard, dyskinesier, förvirrad, lätt acidos, orolig, hallucinationer. "blodgas 7.30, pco2 7,53. BE 1.7"
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Labvärde, referens saknas.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 30/MAY/2018 - 30/MAY/2018
Seq No	:	2
Drug	:	Equasym Depot 20 mg Kapsel med modifierad frisättning, hård(Equasym Depot)(methylphenidate hydrochloride, methylphenidate)(methylphenidate hydrochloride, methylphenidate)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 30/MAY/2018 - 30/MAY/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				19	Kvinna	20	SEP	2018	

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

SKAKAR (Shaking) - Okänd
Protocol relatedness:
As per reporter:
As per company:

OROLIG (Anxiety) - Okänd
Protocol relatedness:

Cont...

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine
2) venlafaxine(Venlafaxine)(Venlafaxine)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) (375 Milligram) 2) (187.5 Milligr-	1) Per oral 2) Per oral	☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE	
1)	2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 20/SEP/2018 2) 20/SEP/2018	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER

MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO 2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER 29/MAY/2019

24d REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT 24/JUN/2021

25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	20/Sep/2018
Seq No	:	2
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	20/Sep/2018
Seq No	:	3
Reaction	:	SKAKAR (Shaking)
Start Date	:	20/Sep/2018
Seq No	:	4
Reaction	:	OROLIG (Anxiety)
Start Date	:	20/Sep/2018
Seq No	:	5
Reaction	:	TRÖTT (Tiredness)
Start Date	:	20/Sep/2018
Seq No	:	6
Reaction	:	TAKYKARD PULS 120 (Tachycardia)
Start Date	:	20/Sep/2018
Seq No	:	7
Reaction	:	LITE SYNHALLUCINOS (Visual hallucinations)
Start Date	:	20/Sep/2018
Seq No	:	8
Reaction	:	NEDSATT VISUS (Visual disturbance NOS)
Start Date	:	20/Sep/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

TRÖTT (Tiredness) - Okänd
Protocol relatedness:
As per reporter:
As per company:

TAKYKARD PULS 120 (Tachycardia) - Tillfrisknat utan men
Protocol relatedness:
As per reporter:
As per company:

LITE SYNHALLUCINOS (Visual hallucinations) - Tillfrisknat utan men
Protocol relatedness:
As per reporter:
As per company:

NEDSATT VISUS (Visual disturbance NOS) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 19-årig kvinna.
Rapporterat misstänkt läkemedel var Lergigan (promethazine), venlafaxine. Rapporterat som avsiktlig självdes truktiv handling, avsiktlig överdosering, skakar,
orolig, trött, takykard puls 120, lite synhallucinos, nedsatt visus.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 20/SEP/2018 - 20/SEP/2018
Seq No	:	2
Drug	:	venlafaxine(Venlafaxine)(Venlafaxine)
Daily Dose	:	1) (187.5 Milligram)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 20/SEP/2018 - 20/SEP/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR
	SVERIGE				16	Man	30	MAY	2018

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

LITE ARG (Anger) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

Cont...

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine
2) citalopram(Citalopram)(Citalopram)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) "5 mg ca 10 st - 2) (45 Milligram)	1) Per oral 2)	☐ YES ☐ NO ☐ NA
17 INDICATIONS FOR USE 1) 2)		
18 THERAPY DATES(From/To) 1) 30/MAY/2018 2) 30/MAY/2018	19 THERAPY DURATION 1) 2)	

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER

MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO 2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER 29/MAY/2019

24d REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT 24/JUN/2021

25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	30/May/2018
Seq No	:	2
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	30/May/2018
Seq No	:	3
Reaction	:	LITE ARG (Anger)
Start Date	:	30/May/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 16-årig pojke. Den medicinska historien inkluderade depression.
Rapporterat misstänkt läkemedel var Lergigan (promethazine), citalopram. Rapporterat som avsiktlig överdosering, avsiktlig självdestruktiv handling, lite arg.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Daily Dose	:	1) "5 mg ca 10 st en näve"
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 30/MAY/2018 - 30/MAY/2018
Seq No	:	2
Drug	:	citalopram(Citalopram)(Citalopram)
Therapy Dates/Duration	:	1) 30/MAY/2018 - 30/MAY/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted] (0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				16	Man	31	MAY	2018	

7 +13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 16-årig pojke.
Rapporterat misstänkt läkemedel var Lergigan (promethazine), citalopram, melato

Cont...

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine
2) melatonin(Melatonin)(Melatonin)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) "15 st 5 mg bli- 2) "oklart hur må-	1) Per oral 2)	☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 31/MAY/2018 2) 31/MAY/2018	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted] (0)

24c DATE RECEIVED BY MANUFACTURER	24d REPORT SOURCE
29/MAY/2019	☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER
DATE OF THIS REPORT 24/JUN/2021	25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	31/May/2018
Seq No	:	2
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	31/May/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

nin. Rapporterat som avsiktlig överdosering, avsiktlig självdestruktiv handling.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Daily Dose	:	1) "15 st 5 mg blir 75 mg"
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 31/MAY/2018 - 31/MAY/2018
Seq No	:	2
Drug	:	melatonin(Melatonin)(Melatonin)
Daily Dose	:	1) "oklart hur många"
Therapy Dates/Duration	:	1) 31/MAY/2018 - 31/MAY/2018
Seq No	:	3
Drug	:	citalopram(Citalopram)(Citalopram)
Daily Dose	:	1) "står på 20 mg 4 st"
Therapy Dates/Duration	:	1) 31/MAY/2018 - 31/MAY/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				17		17	DEC	2018	

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

SOMNOLENT (Somnolence) - Okänd
Protocol relatedness:
As per reporter:
As per company:

INTE KONTAKTBAR (Unresponsive to stimuli) - Okänd
Protocol relatedness:

Cont...

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Propavan(propiomazine maleate, propiomazine)(propiomazine maleate,
2) escitalopram(Escitalopram)(Escitalop-
Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION
1) "i larmet står- 2) "oklara mängde-	1) Per oral 2) Per oral

21 DID EVENT REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1)
2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 17/DEC/2018 2) 17/DEC/2018	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER	24d REPORT SOURCE
29/MAY/2019	☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER
DATE OF THIS REPORT 24/JUN/2021	25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	17/Dec/2018
Seq No	:	2
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	17/Dec/2018
Seq No	:	3
Reaction	:	SOMNOLENT (Somnolence)
Start Date	:	17/Dec/2018
Seq No	:	4
Reaction	:	INTE KONTAKTBAR (Unresponsive to stimuli)
Start Date	:	17/Dec/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 17-åring, motstridiga uppgifter angående kön.
Rapporterat misstänkt läkemedel var Propavan (propiomazine), alimemazine, escitalopram. Det står "propavan (
i larmet står 13 propavan)
kan ha tagit det
escitalopram
alimemazine
oklara mängder
dosetten är tom".
Rapporterat som avsiktlig självdestruktiv handling, avsiktlig överdosering. Personen inkom till sjukhus somno
lent och "inte kontaktbar", "svarar inte på tilltal 110 i puls".
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Propavan(propiomazine maleate, propiomazine)(propiomazine maleate, propiomazine)
Daily Dose	:	1) "i larmet står 13 propavan" "oklara mängder dosetten är tom"
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 17/DEC/2018 - 17/DEC/2018
Seq No	:	2
Drug	:	escitalopram(Escitalopram)(Escitalopram)
Daily Dose	:	1) "oklara mängder dosetten är tom"
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 17/DEC/2018 - 17/DEC/2018
Seq No	:	3
Drug	:	alimemazine(Alimemazine)(Alimemazine)
Daily Dose	:	1) "oklara mängder dosetten är tom"
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 17/DEC/2018 - 17/DEC/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR
	SVERIGE				17	Kvinna	14	MAY	2018

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

LITE MEDVETANDESÄNKT (Consciousness decreased) - Okänd
Protocol relatedness:
As per reporter:
As per company:

OROLIG (Anxiety) - Okänd
Protocol relatedness:

Cont...

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Propavan(propiomazine maleate, propiomazine)(propiomazine maleate,
2) escitalopram(Escitalopram)(Escitalop-
Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE
1) "verkar- ha tag- 2) "kanske 140 mg"

16 ROUTE OF ADMINISTRATION
1) Per oral 2) Per oral

21 DID EVENT REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1)
2)

18 THERAPY DATES(From/To)
1) 14/MAY/2018 2) 14/MAY/2018

19 THERAPY DURATION
1)
2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER
29/MAY/2019

24d REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
24/JUN/2021

25a REPORT TYPE
☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	14/May/2018
Seq No	:	2
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	14/May/2018
Seq No	:	3
Reaction	:	LITE MEDVETANDESÄNKT (Consciousness decreased)
Start Date	:	14/May/2018
Seq No	:	4
Reaction	:	OROLIG (Anxiety)
Start Date	:	14/May/2018
Seq No	:	5
Reaction	:	URINRETENTION (Urinary retention)
Start Date	:	14/May/2018
Seq No	:	6
Reaction	:	TAKYKARD (Tachycardia)
Start Date	:	14/May/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

URINRETENTION (Urinary retention) - Okänd
Protocol relatedness:
As per reporter:
As per company:

TAKYKARD (Tachycardia) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 17-årig flicka.
Rapporterat misstänkt läkemedel var Propavan (propiomazine), escitalopram. Även "lite cannabis". Intag "måste ha skett mellan 10-12, tror dem".
Rapporterat som avsiktlig överdosering, avsiktlig självdestruktiv handling. Vid kl 15.15 beskrivs flickan som lite medvetandesänkt, orolig, "ryckig i kroppen", urinretention, takykard "130".
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Propavan(propiomazine maleate, propiomazine)(propiomazine maleate, propiomazine)
Daily Dose	:	1) "verkar- ha tagit några kartor propavan", "1300 mg propavan"
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 14/MAY/2018 - 14/MAY/2018
Seq No	:	2
Drug	:	escitalopram(Escitalopram)(Escitalopram)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 14/MAY/2018 - 14/MAY/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted] (0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				14	Kvinna	18	JAN	2018	

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

YRSEL (Dizziness) - Okänd
Protocol relatedness:
As per reporter:
As per company:

ONT I HUVUDET (Pain head) - Okänd
Protocol relatedness:

Cont...

☐ PATIENT DIED
☐ LIFE THREATENING
☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
☐ CONGENITAL ANOMALY
☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine
2) sertraline(Sertraline)(Sertraline)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) (500 Milligram) 2) (400 Milligram)	1) Per oral 2) Per oral	☐ YES ☐ NO ☐ NA
17 INDICATIONS FOR USE 1) 2)		
18 THERAPY DATES(From/To) 1) 18/JAN/2018 2) 18/JAN/2018	19 THERAPY DURATION 1) 2)	

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER

MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO 2019-[redacted] (0)

24c DATE RECEIVED BY MANUFACTURER 29/MAY/2019

24d REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT 24/JUN/2021

25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	18/Jan/2018
Seq No	:	2
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	18/Jan/2018
Seq No	:	3
Reaction	:	YRSEL (Dizziness)
Start Date	:	18/Jan/2018
Seq No	:	4
Reaction	:	ONT I HUVUDET (Pain head)
Start Date	:	18/Jan/2018
Seq No	:	5
Reaction	:	BRÖSTSMÄRTA (Chest pain)
Start Date	:	18/Jan/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

BRÖSTSMÄRTA (Chest pain) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 14-årig flicka.
Rapporterat misstänkt läkemedel var Lergigan (promethazine), sertraline. Rapporterat som avsiktlig överdoser
ing, avsiktlig självdestruktiv handling. Cirka 13 timmar efter intag beskrivs flickan ha yrsel, ont i huvudet,
bröstsmärta.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 18/JAN/2018 - 18/JAN/2018
Seq No	:	2
Drug	:	sertraline(Sertraline)(Sertraline)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 18/JAN/2018 - 18/JAN/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				15	Kvinna	14	MAR	2018	

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 15-årig flicka.
Rapporterat misstänkt läkemedel var Concerta (methylphenidate), Lamictal (lamot

Cont...

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine
2) Lamictal(lamotrigine)(lamotrigine)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) 2)	1) Per oral 2) Per oral	☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 14/MAR/2018 2) 14/MAR/2018	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER	24d REPORT SOURCE
29/MAY/2019	☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER
DATE OF THIS REPORT 24/JUN/2021	25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	14/Mar/2018
Seq No	:	2
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	14/Mar/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

rigine), Lergigan (promethazine), Tikacillin (phenoxymethylpenicillin),
escitalopram, methylphenidate. Gällande mängd intagen framkommer ur rapport "oklar mängd totalt 1,5 näve".

Kvinnan "stabil, redig och pratglad". Har fått kol.

Rapporterat som avsiktlig självdestruktiv handling, avsiktlig överdosering.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 14/MAR/2018 - 14/MAR/2018
Seq No	:	2
Drug	:	Lamictal(lamotrigine)(lamotrigine)
Route of Admin	:	1) Per oral 2) Per oral
Therapy Dates/Duration	:	1) 14/MAR/2018 - 14/MAR/2018 2) 14/MAR/2018 - 14/MAR/2018
Seq No	:	3
Drug	:	Concerta(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride, methylphenidate hydrochloride, methylphenidate)(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride, methylphenidate hydrochloride, methylphenidate)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 14/MAR/2018 - 14/MAR/2018
Seq No	:	4
Drug	:	methylphenidate(Methylphenidate)(Methylphenidate)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 14/MAR/2018 - 14/MAR/2018
Seq No	:	5
Drug	:	escitalopram(Escitalopram)(Escitalopram)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 14/MAR/2018 - 14/MAR/2018
Seq No	:	6
Drug	:	Tikacillin(phenoxymethylpenicillin potassium, phenoxymethylpenicillin)(phenoxymethylpenicillin potassium, phenoxymethylpenicillin)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 14/MAR/2018 - 14/MAR/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				14	Kvinna	14	NOV	2018	

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

KRÄKTS (Vomited) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

Cont...

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine
2) sertraline(Sertraline)(Sertraline)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) 2)	1) Per oral 2) Per oral	☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 14/NOV/2018 2) 14/NOV/2018	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER

MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER	24d REPORT SOURCE
29/MAY/2019	☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER
DATE OF THIS REPORT 24/JUN/2021	25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	14/Nov/2018
Seq No	:	2
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	14/Nov/2018
Seq No	:	3
Reaction	:	KRÄKTS (Vomited)
Start Date	:	14/Nov/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 14-årig flicka.
Rapporterat misstänkt läkemedel var Lergigan (promethazine), melatonin, sertraline, oklart hur mycket. Rapporterat som avsiktlig överdosering, avsiktlig självdestruktiv handling. Flickan hade "kräkts en del".
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 14/NOV/2018 - 14/NOV/2018
Seq No	:	2
Drug	:	sertraline(Sertraline)(Sertraline)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 14/NOV/2018 - 14/NOV/2018
Seq No	:	3
Drug	:	melatonin(Melatonin)(Melatonin)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 14/NOV/2018 - 14/NOV/2018

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR
	SVERIGE				13	Kvinna	13	MAY	2018

7 +13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

HÖG PULS 132 (Pulse rate increased) - Okänd
Protocol relatedness:
As per reporter:
As per company:

MOTORISK OROLIG, PLOCKIG (Motor restlessness) - Okänd
Protocol relatedness:

Cont...

8 -12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Propavan(propiomazine maleate, propiomazine)(propiomazine maleate,
2) sertraline(Sertraline)(Sertraline)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE
1) (300 Milligram) 2) (150 Milligram)

16 ROUTE OF ADMINISTRATION
1) Per oral 2) Per oral

21 DID EVENT REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)
1) 13/MAY/2018 2) 13/MAY/2018

19 THERAPY DURATION
1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER

MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER
29/MAY/2019

24d REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
24/JUN/2021

25a REPORT TYPE
☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	13/May/2018
Seq No	:	2
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	13/May/2018
Seq No	:	3
Reaction	:	HÖG PULS 132 (Pulse rate increased)
Start Date	:	13/May/2018
Seq No	:	4
Reaction	:	MOTORISK OROLIG, PLOCKIG (Motor restlessness)
Start Date	:	13/May/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 13-årig flicka.
Rapporterat misstänkt läkemedel var Lergigan (promethazine), Propavan (propiomazine), sertraline. Rapporterat som avsiktlig självdestruktiv handling, avsiktlig
överdosering, hög puls 132, motorisk orolig, plockig. Dessa symtom såg inom ca 3 timmar efter intag. Ytterli gare några timmar senare har flickan "lugnat ner sig".
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Propavan(propiomazine maleate, propiomazine)(propiomazine maleate, propiomazine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 13/MAY/2018 - 13/MAY/2018
Seq No	:	2
Drug	:	sertraline(Sertraline)(Sertraline)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 13/MAY/2018 - 13/MAY/2018
Seq No	:	3
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Daily Dose	:	1) (50 Milligram)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 13/MAY/2018 - 13/MAY/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				17	Kvinna	10	OCT	2018	

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

SKAKIG (Shakiness) - Okänd
Protocol relatedness:
As per reporter:
As per company:

SVÅRT ATT FOKUSERA (Disturbance in attention) - Okänd
Protocol relatedness:

Cont...

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine
2) Circadin(melatonin)(melatonin)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) (250 Milligram) 2) (10 Milligram)	1) Per oral 2) Per oral	☐ YES ☐ NO ☐ NA
17 INDICATIONS FOR USE 1) 2)		
18 THERAPY DATES(From/To) 1) 10/OCT/2018 2) 10/OCT/2018	19 THERAPY DURATION 1) 2)	

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER

MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO 2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER 29/MAY/2019

24d REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT 24/JUN/2021

25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	10/Oct/2018
Seq No	:	2
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	10/Oct/2018
Seq No	:	3
Reaction	:	SKAKIG (Shakiness)
Start Date	:	10/Oct/2018
Seq No	:	4
Reaction	:	SVÅRT ATT FOKUSERA (Disturbance in attention)
Start Date	:	10/Oct/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 17-årig flicka.

Rapporterat misstänkt läkemedel var 10 mg Circadin (melatonin), 250 mg Lergigan (promethazine), "8 mg x 5" me latonin, 500 mg sertraline. Vid ankomst till sjukhus, ca 20 minuter efter intaget, rapporterat som avsiktlig överdosering, avsiktlig självdestruktiv handling. Flickan är skakig, haft svårt att fokusera.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 10/OCT/2018 - 10/OCT/2018
Seq No	:	2
Drug	:	Circadin(melatonin)(melatonin)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 10/OCT/2018 - 10/OCT/2018
Seq No	:	3
Drug	:	melatonin(Melatonin)(Melatonin)
Daily Dose	:	1) "8 mg x 5"
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 10/OCT/2018 - 10/OCT/2018
Seq No	:	4
Drug	:	sertraline(Sertraline)(Sertraline)
Daily Dose	:	1) (500 Milligram)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 10/OCT/2018 - 10/OCT/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				14	Kvinna	07	NOV	2016	

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

SKAKIG (Shakiness) - Okänd
Protocol relatedness:
As per reporter:
As per company:

SNABB PULS (Pulse rapid) - Okänd
Protocol relatedness:

Cont...

☐ PATIENT DIED
☐ LIFE THREATENING
☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
☐ CONGENITAL ANOMALY
☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)
1) Cocillana-Etyfin(cocillana, fluid extract, senega extract,
2) sertraline(Sertraline)(Sertraline)
Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE
1) "Cirka 100 ml" 2) "250"

16 ROUTE OF ADMINISTRATION
1) Per oral 2)

21 DID EVENT REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)
1) 07/NOV/2016 2)

19 THERAPY DURATION
1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)
Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY
No Risk Factor Available
Past Disease:
SJÄLVMORDSBENÄGEN

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER
04/FEB/2019

24d REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
24/JUN/2021

25a REPORT TYPE
☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	07/Nov/2016
Seq No	:	2
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	07/Nov/2016
Seq No	:	3
Reaction	:	SKAKIG (Shakiness)
Start Date	:	07/Nov/2016
Seq No	:	4
Reaction	:	SNABB PULS (Pulse rapid)
Start Date	:	07/Nov/2016

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 14-årig flicka. Den medicinska historien inkluderade tidigare "självmordsbenägen".
Rapporterat misstänkt läkemedel var Cocillana-Etyfin (cocillanaextrakt, senegaextrakt samt etylmorfinhydroklorid) cirka 100 ml. Cirka 30 minuter tidigare har hon tagit sin "vanliga dos" Atarax "12,5" (hydroxyzine), Tetralysal (lymecycline) och sertraline "250".
Rapporterat som avsiktlig överdosering, avsiktlig självdestruktiv handling. Efter cirka 1,5 timmar är hon "skakig", "snabb puls men efter ett tag blev pulsen bättre". Rekommenderas uppsöka sjukvård.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Cocillana-Etyfin(cocillana, fluid extract, senega extract, ethylmorphine hydrochloride, ethylmorphine)(cocillana, fluid extract, senega extract, ethylmorphine hydrochloride, ethylmorphine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 07/NOV/2016 - 07/NOV/2016
Seq No	:	3
Drug	:	Atarax(hydroxyzine hydrochloride, hydroxyzine)(hydroxyzine hydrochloride, hydroxyzine)
Daily Dose	:	1) "12,5"
Seq No	:	4
Drug	:	Tetralysal(lymecycline, tetracycline)(lymecycline, tetracycline)

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted] (0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR
	SVERIGE				18	Man	05	MAY	2019

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 18-årig man.
Rapporterat misstänkt läkemedel var 200 mg Lergigan (promethazine), 60 mg deslo

Cont...

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine
2) escitalopram(Escitalopram) (Escitalop-

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE
1) 200 Milligram (- 2) 140 Milligram (-

16 ROUTE OF ADMINISTRATION
1) Per oral 2) Per oral

21 DID EVENT REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)
1) 05/MAY/2019 2) 05/MAY/2019

19 THERAPY DURATION
1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted] (0)

24c DATE RECEIVED BY MANUFACTURER
29/MAY/2019

24d REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
24/JUN/2021

25a REPORT TYPE
☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	05/May/2019
Seq No	:	2
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	05/May/2019

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

ratadine, 140 mg escitalopram. Rapporterat som avsiktlig överdosering, avsiktlig självdestruktiv handling. Ci
rka 3 timmar efter intag mår mannen ganska bra med stabila parametrar.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Daily Dose	:	1) 200 Milligram (200 Milligram,1 in 1 En gång)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 05/MAY/2019 - 05/MAY/2019
Seq No	:	2
Drug	:	escitalopram(Escitalopram)(Escitalopram)
Daily Dose	:	1) 140 Milligram (140 Milligram,1 in 1 En gång)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 05/MAY/2019 - 05/MAY/2019
Seq No	:	3
Drug	:	desloratadine(Desloratadine)(Desloratadine)
Daily Dose	:	1) 60 Milligram (60 Milligram,1 in 1 En gång)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 05/MAY/2019 - 05/MAY/2019

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted] (0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR
	SVERIGE				19	Man	06	JAN	2018

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

ONT I BRÖSTET (Chest pain) - Tillfrisknat utan men
Protocol relatedness:
As per reporter:
As per company:

SLUDDRIG I TAL (Slurred speech) - Tillfrisknat utan men
Protocol relatedness:

Cont...

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Propavan(propiomazine maleate, propiomazine)(propiomazine maleate,
2) mirtazapine(Mirtazapine)(Mirtazapine)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION
1) (375 Milligram) 2) (150 Milligram)	1) Per oral 2) Per oral

21 DID EVENT REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1)
2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 06/JAN/2018 2) 06/JAN/2018	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER

MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO 2019-[redacted] (0)

24c DATE RECEIVED BY MANUFACTURER 29/MAY/2019

24d REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT 24/JUN/2021

25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	06/Jan/2018
Seq No	:	2
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	06/Jan/2018
Seq No	:	3
Reaction	:	ONT I BRÖSTET (Chest pain)
Start Date	:	06/Jan/2018
Seq No	:	4
Reaction	:	SLUDDRIG I TAL (Slurred speech)
Start Date	:	06/Jan/2018
Seq No	:	5
Reaction	:	LITE IRRITERAD (Irritability)
Start Date	:	07/Jan/2018
Seq No	:	6
Reaction	:	ANDAS SAKTA (Breathing slowed)
Start Date	:	06/Jan/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

LITE IRRITERAD (Irritability) - Okänd
Protocol relatedness:
As per reporter:
As per company:

ANDAS SAKTA (Breathing slowed) - Tillfrisknat utan men
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 19-årig man.
Rapporterat misstänkt läkemedel var Propavan (propiomazine), mirtazapine.
Rapporterat som avsiktlig självdestruktiv handling, avsiktlig överdosering, ont i bröstet, sluddrig i tal, andas sakta.
Enligt rapport daterad cirka 4 timmar efter intag framkommer "cirk resp stabil, hjärta ua inga symtom, lite irriterad, RLS 1".

Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Propavan(propiomazine maleate, propiomazine)(propiomazine maleate, propiomazine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 06/JAN/2018 - 06/JAN/2018
Seq No	:	2
Drug	:	mirtazapine(Mirtazapine)(Mirtazapine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 06/JAN/2018 - 06/JAN/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted] (0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				19	Man	30	JUN	2019	

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 19-årig man.
Rapporterat misstänkt läkemedel var Lergigan (promethazine), Propavan (propioma

Cont...

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine
2) sertraline(Sertraline)(Sertraline)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) (375 Milligram) 2) (1250 Milligra-	1) Per oral 2) Per oral	☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1)
2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 30/JUN/2019 2) 30/JUN/2019	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted] (0)

24c DATE RECEIVED BY MANUFACTURER	24d REPORT SOURCE
03/AUG/2019	☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER
DATE OF THIS REPORT 24/JUN/2021	25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	30/Jun/2019
Seq No	:	2
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	30/Jun/2019

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

zine), sertraline. Rapporterat som avsiktlig självdestruktiv handling, avsiktlig
överdosering.
Ur rapport "rls 3-4 fluktuerande" samt "alkohol".
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 30/JUN/2019 - 30/JUN/2019
Seq No	:	2
Drug	:	sertraline(Sertraline)(Sertraline)
Daily Dose	:	1) (1250 Milligram)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 30/JUN/2019 - 30/JUN/2019
Seq No	:	3
Drug	:	Propavan(propiomazine maleate, propiomazine)(propiomazine maleate, propiomazine)
Daily Dose	:	1) (750 Milligram)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 30/JUN/2019 - 30/JUN/2019

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				15	Kvinna	29	JAN	2019	

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

PSYKOSLIKNANDE SYMTOM (Psychotic symptom) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AGITERAD (Agitated) - Okänd
Protocol relatedness:

Cont...

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine

2) Atarax(hydroxyzine hydrochloride, hydroxyzine)(hydroxyzine

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE
1) "10 tabletter o- 2)

16 ROUTE OF ADMINISTRATION
1) Per oral 2) Per oral

21 DID EVENT REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)
1) 29/JAN/2019 2) 29/JAN/2019

19 THERAPY DURATION
1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER
29/MAY/2019

24d REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
24/JUN/2021

25a REPORT TYPE
☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	29/Jan/2019
Seq No	:	2
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	29/Jan/2019
Seq No	:	3
Reaction	:	PSYKOSLIKNANDE SYMTOM (Psychotic symptom)
Start Date	:	29/Jan/2019
Seq No	:	4
Reaction	:	AGITERAD (Agitated)
Start Date	:	29/Jan/2019
Seq No	:	5
Reaction	:	VÄXLANDE I ORIENTERINGSGRAD (Orientation disturbed)
Start Date	:	29/Jan/2019
Seq No	:	6
Reaction	:	FÖRMODLIGEN HALLUCINERAR (Hallucination)
Start Date	:	29/Jan/2019
Seq No	:	7
Reaction	:	AGGRESSIV (Aggressiveness)
Start Date	:	29/Jan/2019

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

VÄXLANDE I ORIENTERINGSGRAD (Orientation disturbed) - Okänd
Protocol relatedness:
As per reporter:
As per company:

FÖRMODLIGEN HALLUCINERAR (Hallucination) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AGGRESSIV (Aggressiveness) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 15-årig flicka. Det står "viss impulsivitet i grundsjukd om".
Rapporterat misstänkt läkemedel var 10 Lergigan (promethazine) samt okänd mängd Atarax (hydroxyzine), Elvan se (lisdexamfetamine), fluoxetine, melatonin och/eller omeprazole. Rapporterat som avsiktlig överdosering, avs iktlig självdestruktiv handling. Flickan fick psykosliknande symtom, agiterad, växlande i orienteringsgrad, " förmodligen hallucinerar", aggressiv (hade slagit på dörrar), "påverkad". "blodprover ua", "urindrogscreeni ng normala värden".
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Daily Dose	:	1) "10 tabletter okänd styrka"
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 29/JAN/2019 - 29/JAN/2019
Seq No	:	2
Drug	:	Atarax(hydroxyzine hydrochloride, hydroxyzine)(hydroxyzine hydrochloride, hydroxyzine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 29/JAN/2019 - 29/JAN/2019
Seq No	:	3
Drug	:	melatonin(Melatonin)(Melatonin)
Route of Admin	:	1) Per oral 2) Per oral
Therapy Dates/Duration	:	1) 29/JAN/2019 - 29/JAN/2019 2) 29/JAN/2019 - 29/JAN/2019
Seq No	:	4
Drug	:	omeprazole(Omeprazole)(Omeprazole)
Route of Admin	:	1) Per oral 2) Per oral
Therapy Dates/Duration	:	1) 29/JAN/2019 - 29/JAN/2019 2) 29/JAN/2019 - 29/JAN/2019

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted] (0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				19	Kvinna	16	SEP	2018	

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

TRÖTT (Tiredness) - Okänd
Protocol relatedness:
As per reporter:
As per company:

TAKYKARD 150-160 (Tachycardia) - Okänd
Protocol relatedness:

Cont...

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Propavan(propiomazine maleate, propiomazine)(propiomazine maleate,

2) sertraline(Sertraline)(Sertraline)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) 2)	1) Per oral 2) Per oral	☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 16/SEP/2018 2) 16/SEP/2018	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted] (0)

24c DATE RECEIVED BY MANUFACTURER
29/MAY/2019

24d REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
24/JUN/2021

25a REPORT TYPE
☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Seq No	:	5
Drug	:	Elvanse(lisdexamfetamine dimesilate, lisdexamfetamine, dexamfetamine)(lisdexamfetamine dimesilate, lisdexamfetamine, dexamfetamine)
Route of Admin	:	1) Per oral 2) Per oral
Therapy Dates/Duration	:	1) 29/JAN/2019 - 29/JAN/2019 2) 29/JAN/2019 - 29/JAN/2019

Seq No	:	6
Drug	:	fluoxetine(Fluoxetine)(Fluoxetine)
Route of Admin	:	1) Per oral 2) Per oral
Therapy Dates/Duration	:	1) 29/JAN/2019 - 29/JAN/2019 2) 29/JAN/2019 - 29/JAN/2019

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	16/Sep/2018
Seq No	:	2
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	16/Sep/2018
Seq No	:	3
Reaction	:	TRÖTT (Tiredness)
Start Date	:	16/Sep/2018
Seq No	:	4
Reaction	:	TAKYKARD 150-160 (Tachycardia)
Start Date	:	16/Sep/2018
Seq No	:	5
Reaction	:	SNARKIG ANDNING (Snoring)
Start Date	:	16/Sep/2018
Seq No	:	6
Reaction	:	SPÄND OCH STEL (Stiffness)
Start Date	:	16/Sep/2018
Seq No	:	7
Reaction	:	MOTORISKT OROLIG (Motor restlessness)
Start Date	:	16/Sep/2018
Seq No	:	8
Reaction	:	HYPERTENSIV (Hypertensive)
Start Date	:	16/Sep/2018
Seq No	:	9
Reaction	:	KRÄKTES (Vomited)
Start Date	:	16/Sep/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

SNARKIG ANDNING (Snoring) - Okänd
Protocol relatedness:
As per reporter:
As per company:

SPÄND OCH STEL (Stiffness) - Okänd
Protocol relatedness:
As per reporter:
As per company:

MOTORISKT OROLIG (Motor restlessness) - Okänd
Protocol relatedness:
As per reporter:
As per company:

HYPERTENSIV (Hypertensive) - Okänd
Protocol relatedness:
As per reporter:
As per company:

KRÄKTES (Vomited) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 19-årig kvinna.
Rapporterat misstänkt läkemedel var Propavan (propiomazine), melatonin, paracetamol, sertraline. Intagen dos ej helt tydligt men nämns i rapport " 30ta sertralin 100 mg 30 st propavan 25 mg en burk melatonin en karta pa racetamol 500 mg".
Rapporterat som avsiktlig självdestruktiv handling, avsiktlig överdosering, trött, takykard 150-160, snarkig andning, spänd och stel, motoriskt orolig, hypertensiv, kräktes.
Kvinnan intuberas. Rapport daterad ca 4-5 timmar efter intag
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Propavan(propiomazine maleate, propiomazine)(propiomazine maleate, propiomazine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 16/SEP/2018 - 16/SEP/2018
Seq No	:	2
Drug	:	sertraline(Sertraline)(Sertraline)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 16/SEP/2018 - 16/SEP/2018

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Seq No	:	3
Drug	:	melatonin(Melatonin)(Melatonin)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 16/SEP/2018 - 16/SEP/2018

Seq No	:	4
Drug	:	paracetamol(Paracetamol)(Paracetamol)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 16/SEP/2018 - 16/SEP/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR
	SVERIGE				17	Kvinna	25	APR	2018

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

HALLUCINERAR (Hallucinating) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

Cont...

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine
2) Zyprexa(olanzapine)(olanzapine)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) 2)	1) Per oral 2) Per oral	☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 25/APR/2018 2) 25/APR/2018	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER

MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO 2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER 29/MAY/2019

24d REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT 24/JUN/2021

25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	25/Apr/2018
Seq No	:	2
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	25/Apr/2018
Seq No	:	3
Reaction	:	HALLUCINERAR (Hallucinating)
Start Date	:	25/Apr/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 17-årig flicka.
Rapporterat misstänkt läkemedel var Lergigan (promethazine), Zyprexa (olanzapine), fluoxetine, melatonin. Fra mkommer ej intagen mängd eller tidpunkt för intag.
Rapporterat som avsiktlig överdosering, avsiktlig självdestruktiv handling. Kvinnan är "plockig o inte med, hallucinerar, blivit mer borta än vanliga". Bedöms om "mest troligt lergigansymtom - d v s centrala antikolin erga symtom".
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 25/APR/2018 - 25/APR/2018
Seq No	:	2
Drug	:	Zyprexa(olanzapine)(olanzapine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 25/APR/2018 - 25/APR/2018
Seq No	:	3
Drug	:	fluoxetine(Fluoxetine)(Fluoxetine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 25/APR/2018 - 25/APR/2018
Seq No	:	4
Drug	:	melatonin(Melatonin)(Melatonin)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 25/APR/2018 - 25/APR/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				15	Kvinna	28	JAN	2018	

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

KRÅKTES (Vomited) - Okänd
Protocol relatedness:
As per reporter:
As per company:

TRÖTT (Tiredness) - Okänd
Protocol relatedness:

Cont...

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Propavan(propiomazine maleate, propiomazine)(propiomazine maleate,
2) Atarax(hydroxyzine hydrochloride, hydroxyzine)(hydroxyzine

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE
1) 20 st (500 Mill- 2) 5 st

16 ROUTE OF ADMINISTRATION
1) Per oral 2)

17 INDICATIONS FOR USE
1) 2)

21 DID EVENT REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

18 THERAPY DATES(From/To)
1) 28/JAN/2018 2) 28/JAN/2018

19 THERAPY DURATION
1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

Informed EMA

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER
29/MAY/2019

24d REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
24/JUN/2021

25a REPORT TYPE
☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	28/Jan/2018
Seq No	:	2
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	28/Jan/2018
Seq No	:	3
Reaction	:	KRÄKTES (Vomited)
Start Date	:	28/Jan/2018
Seq No	:	4
Reaction	:	TRÖTT (Tiredness)
Start Date	:	28/Jan/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 15-årig flicka.
Rapporterat misstänkt läkemedel var Atarax (hydroxyzine), Propavan (propiomazine), melatonin, sertraline. Rapporterat som avsiktlig självdestruktiv handling,
avsiktlig överdosering. Flickan kräktes 20 minuter efter intaget, "tablettrest i kräks".
Ca 45 minuter efter intaget kom flickan till akuten och fick kol direkt. Vid kontakt med
Giftinformationscentralen efter ytterligare ett par timmar är flickan trött och vill sova, "inga andra symtom", "mår bra".
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Propavan(propiomazine maleate, propiomazine)(propiomazine maleate, propiomazine)
Daily Dose	:	1) 20 st (500 Milligram)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 28/JAN/2018 - 28/JAN/2018
Seq No	:	2
Drug	:	Atarax(hydroxyzine hydrochloride, hydroxyzine)(hydroxyzine hydrochloride, hydroxyzine)
Therapy Dates/Duration	:	1) 28/JAN/2018 - 28/JAN/2018
Seq No	:	3
Drug	:	sertraline(Sertraline)(Sertraline)
Daily Dose	:	1) 5 st á 50 mg (250 Milligram)
Therapy Dates/Duration	:	1) 28/JAN/2018 - 28/JAN/2018
Seq No	:	4
Drug	:	melatonin(Melatonin)(Melatonin)
Daily Dose	:	1) oklar mängd
Therapy Dates/Duration	:	1) 28/JAN/2018 - 28/JAN/2018

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4 -6 REACTION ONSET DA	MO	YR	8 -12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				18	Man	27	APR	2018	

7 +13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

TAKYKARD (Tachycardia) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

Cont...

☐ PATIENT DIED
☐ LIFE THREATENING
☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
☐ CONGENITAL ANOMALY
☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Propavan(propiomazine maleate, propiomazine)(propiomazine maleate,
2) sertraline(Sertraline)(Sertraline)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) 30 tabletter á- 2) 10 tabletter á-	1) Per oral 2)	☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 27/APR/2018 2) 27/APR/2018	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER	24d REPORT SOURCE
29/MAY/2019	☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER
DATE OF THIS REPORT 24/JUN/2021	25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	27/Apr/2018
Seq No	:	2
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	27/Apr/2018
Seq No	:	3
Reaction	:	TAKYKARD (Tachycardia)
Start Date	:	27/Apr/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 18-årig man.
Rapporterat misstänkt läkemedel var Propavan (propiomazine) och sertraline. Rapporterat som avsiktlig självd estruktiv handling, avsiktlig överdosering.
Läkare på sjukhus kontaktar Giftinformationscentralen 30-40 minuter efter intaget. Mannen beskrivs då som va ken, orienterad, lite orolig, takykard och "stabil i trycket".
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Propavan(propiomazine maleate, propiomazine)(propiomazine maleate, propiomazine)
Daily Dose	:	1) 30 tabletter á 25 mg (750 Milligram)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 27/APR/2018 - 27/APR/2018
Seq No	:	2
Drug	:	sertraline(Sertraline)(Sertraline)
Daily Dose	:	1) 10 tabletter á 50 mg (500 Milligram)
Therapy Dates/Duration	:	1) 27/APR/2018 - 27/APR/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR
	SVERIGE				19	Man	14	SEP	2018

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

SMÅ PUPILLER (Constricted pupils) - Okänd
Protocol relatedness:
As per reporter:
As per company:

ONT I MAGEN (Abdominal pain) - Okänd
Protocol relatedness:

Cont...

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Propavan(propiomazine maleate, propiomazine)(propiomazine maleate,
2) Imovane(zopiclone)(zopiclone)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION
1)	1) Per oral
2)	2) Per oral

21 DID EVENT REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1)
2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 14/SEP/2018	1)
2) 14/SEP/2018	2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER

MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER	24d REPORT SOURCE
29/MAY/2019	☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER
DATE OF THIS REPORT: 24/JUN/2021	25a REPORT TYPE: ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	14/Sep/2018
Seq No	:	2
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	14/Sep/2018
Seq No	:	3
Reaction	:	SMÅ PUPILLER (Constricted pupils)
Start Date	:	14/Sep/2018
Seq No	:	4
Reaction	:	ONT I MAGEN (Abdominal pain)
Start Date	:	14/Sep/2018
Seq No	:	5
Reaction	:	SNABB ANDNINGSFREKVENS (Breathing rate increased)
Start Date	:	14/Sep/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

SNABB ANDNINGSFREKVENS (Breathing rate increased) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 19-årig man.
Rapporterat misstänkt läkemedel var Imovane (zopiclone), Oxascand (oxazepam), Propavan (propiomazine), sertra
line. Intagen mängd av dessa okänt. Rapporterat som avsiktlig självdestruktiv handling, avsiktlig överdoser
ing, små pupiller, ont i magen, snabb andningsfrekvens. Vidare ur rapport "reaktiva pupiller RLS 1". Rapport d
aterad drygt 2 timmar efter intag.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Propavan(propiomazine maleate, propiomazine)(propiomazine maleate, propiomazine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 14/SEP/2018 - 14/SEP/2018
Seq No	:	2
Drug	:	Imovane(zopiclone)(zopiclone)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 14/SEP/2018 - 14/SEP/2018
Seq No	:	3
Drug	:	Oxascand(oxazepam)(oxazepam)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 14/SEP/2018 - 14/SEP/2018
Seq No	:	4
Drug	:	sertraline(Sertraline)(Sertraline)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 14/SEP/2018 - 14/SEP/2018

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR
	SVERIGE				18	Kvinna	27	APR	2018

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

MOTORISKT OROLIG (Motor restlessness) - Okänd
Protocol relatedness:
As per reporter:
As per company:

RLS 2 (Consciousness decreased) - Okänd
Protocol relatedness:

Cont...

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine
2) alimemazine(Alimemazine)(Alimemazine)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) 2)	1) Per oral 2) Per oral	☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 27/APR/2018 2) 27/APR/2018	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER

MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR. CONTROL NO 2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER 29/MAY/2019

24d REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT 24/JUN/2021

25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	27/Apr/2018
Seq No	:	2
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	27/Apr/2018
Seq No	:	3
Reaction	:	MOTORISKT OROLIG (Motor restlessness)
Start Date	:	27/Apr/2018
Seq No	:	4
Reaction	:	RLS 2 (Consciousness decreased)
Start Date	:	27/Apr/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 18-årig kvinna med känd depression.
Rapporterat misstänkt läkemedel var Lergigan (promethazine), alimemazine, fluoxetine. Rapporterat som avsiktl
ig överdosering, avsiktlig självdestruktiv handling.
Kvinnan blev motoriskt orolig, "var ej sig själv". "tror att hon tagit lergigan. vet ej mängd eller vilka and
ra läkemedel hon tagit". På sjukhuset "Kan ej få kontakt med henne, RLS 2 semivaken, väldigt motoriskt orol
ig i perioder. 130 i puls, normalstora pupiller".
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 27/APR/2018 - 27/APR/2018
Seq No	:	2
Drug	:	alimemazine(Alimemazine)(Alimemazine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 27/APR/2018 - 27/APR/2018
Seq No	:	3
Drug	:	fluoxetine(Fluoxetine)(Fluoxetine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 27/APR/2018 - 27/APR/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted] (0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				18	Kvinna	13	APR	2019	

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 18-årig kvinna.
Rapporterat misstänkt läkemedel var "2st" Elvanse (lisdexamfetamine) och "14" L

Cont...

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine

2) Elvanse(lisdexamfetamine dimesilate, lisdexamfetamine,

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) "14" 2) "2st"	1) Per oral 2) Per oral	☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 13/APR/2019 2) 13/APR/2019	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER

MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted] (0)

24c DATE RECEIVED BY MANUFACTURER	24d REPORT SOURCE
29/MAY/2019	☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER
DATE OF THIS REPORT 24/JUN/2021	25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	13/Apr/2019
Seq No	:	2
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	13/Apr/2019

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

ergigan (promethazine). Rapporterat som avsiktlig överdosering, avsiktlig självdestruktiv handling.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 13/APR/2019 - 13/APR/2019
Seq No	:	2
Drug	:	Elvanse(lisdexamfetamine dimesilate, lisdexamfetamine, dexamfetamine)(lisdexamfetamine dimesilate, lisdexamfetamine, dexamfetamine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 13/APR/2019 - 13/APR/2019

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	2 DATE OF BIRTH MO	2 DATE OF BIRTH YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	4-6 REACTION ONSET MO	4-6 REACTION ONSET YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				18	Kvinna	02	MAY	2019	

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 18-årig kvinna.
Rapporterat misstänkt läkemedel var Lergigan (promethazine) "375mg minst" och f

Cont...

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine
2) fluoxetine(Fluoxetine)(Fluoxetine)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) "375mg minst" 2) "100mg minst"	1) Per oral 2) Per oral	☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 02/MAY/2019 2) 02/MAY/2019	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER

MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO 2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER 29/MAY/2019

24d REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT 24/JUN/2021

25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	02/May/2019
Seq No	:	2
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	02/May/2019

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

luoxetine "100mg minst". Rapporterat som avsiktlig överdosering, avsiktlig självdestruktiv handling. Fick kol i ambulansen och på sjukhus "cirk, resp stabil", "mår bra".
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 02/MAY/2019 - 02/MAY/2019
Seq No	:	2
Drug	:	fluoxetine(Fluoxetine)(Fluoxetine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 02/MAY/2019 - 02/MAY/2019

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				12	Kvinna	30	MAY	2018	

7 +13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

LITE TRÖTT (Tiredness) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

Cont...

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine
2) fluoxetine(Fluoxetine)(Fluoxetine)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) "10 st 5 mg" (5- 2) "8 st 20 mg" (1-	1) Per oral 2) Per oral	☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 29/MAY/2018 2) 29/MAY/2018	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER

MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO 2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER	24d REPORT SOURCE
29/MAY/2019	☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER
DATE OF THIS REPORT 24/JUN/2021	25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	30/May/2018
Seq No	:	2
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	30/May/2018
Seq No	:	3
Reaction	:	LITE TRÖTT (Tiredness)
Start Date	:	30/May/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 12-årig flicka.
Rapporterat misstänkt läkemedel var Lergigan (promethazine), fluoxetine. Rapporterat som avsiktlig överdoser
ing, avsiktlig självdestruktiv handling, lite trött.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Daily Dose	:	1) "10 st 5 mg" (50 Milligram)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 29/MAY/2018 - 29/MAY/2018
Seq No	:	2
Drug	:	fluoxetine(Fluoxetine)(Fluoxetine)
Daily Dose	:	1) "8 st 20 mg" (160 Milligram)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 29/MAY/2018 - 29/MAY/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				18	Kvinna	20	MAR	2018	

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

DÅLIGT KONTAKTBAR (Consciousness decreased) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

Cont...

☐ PATIENT DIED
☐ LIFE THREATENING
☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
☐ CONGENITAL ANOMALY
☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Propavan(propiomazine maleate, propiomazine)(propiomazine maleate,
2) Lergigan(promethazine, promethazine

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE 1) 2)

16 ROUTE OF ADMINISTRATION 1) Per oral 2) Per oral

21 DID EVENT REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE 1) 2)

18 THERAPY DATES(From/To) 1) 20/MAR/2018 2) 20/MAR/2018

19 THERAPY DURATION 1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER

MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO 2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER 29/MAY/2019

24d REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT 24/JUN/2021

25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	20/Mar/2018
Seq No	:	2
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	20/Mar/2018
Seq No	:	3
Reaction	:	DÅLIGT KONTAKTBAR (Consciousness decreased)
Start Date	:	20/Mar/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 18-årig kvinna.
Rapporterat misstänkt läkemedel var Lergigan (promethazine), Propavan (propiomazine), duloxetine. Intagen m
ängd av dessa är okänd.
Rapporterat som avsiktlig självdestruktiv handling, avsiktlig överdosering, "dåligt kontaktbar".
Ur rapport framkommer även att kvinnan "krampar".
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
Tidsaspekt okänd.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Propavan(propiomazine maleate, propiomazine)(propiomazine maleate, propiomazine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 20/MAR/2018 - 20/MAR/2018
Seq No	:	2
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 20/MAR/2018 - 20/MAR/2018
Seq No	:	3
Drug	:	duloxetine(Duloxetine)(Duloxetine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 20/MAR/2018 - 20/MAR/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				19	Kvinna	03	JUN	2018	

7 +13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

OROLIG (Anxiety) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

Cont...

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine
2) fluoxetine(Fluoxetine)(Fluoxetine)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1)	1) Per oral	☐ YES ☐ NO ☐ NA
2)	2) Per oral	

17 INDICATIONS FOR USE
1)
2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 30/MAY/2018	1)
2) 30/MAY/2018	2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER	24d REPORT SOURCE
29/MAY/2019	☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER
DATE OF THIS REPORT 24/JUN/2021	25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	03/Jun/2018
Seq No	:	2
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	03/Jun/2018
Seq No	:	3
Reaction	:	OROLIG (Anxiety)
Start Date	:	03/Jun/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 19-årig kvinna.

Rapporterat misstänkt läkemedel var Lergigan (promethazine) och fluoxetine (okänd dos). Kvinnan har även ta
git Lergigan och fluoxetin tre dagar tidigare (okänd dos). Inkommer till sjukhus en timme efter senaste intage
t. Rapporterat som avsiktlig överdosering, avsiktlig självdestruktiv handling. Hon är vaken, orolig, "plocki
g". Råd från Giftinformationscentralen om att avstå från ventrikelsköljning.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Route of Admin	:	1) Per oral 2) Per oral
Therapy Dates/Duration	:	1) 30/MAY/2018 - 30/MAY/2018 2) 03/JUN/2018 - 03/JUN/2018
Seq No	:	2
Drug	:	fluoxetine(Fluoxetine)(Fluoxetine)
Route of Admin	:	1) Per oral 2) Per oral
Therapy Dates/Duration	:	1) 30/MAY/2018 - 30/MAY/2018 2) 03/JUN/2018 - 03/JUN/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted] (0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				15	Kvinna	27	JUL	2018	

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

TRÖTT (Tiredness) - Okänd
Protocol relatedness:
As per reporter:
As per company:

RYCKER I BENEN (Muscle twitching) - Okänd
Protocol relatedness:

Cont...

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine
2) Propavan(propiomazine maleate, propiomazine)(propiomazine maleate,

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) (375 Milligram) 2) (375 Milligram)	1) Per oral 2) Per oral	☐ YES ☐ NO ☐ NA
17 INDICATIONS FOR USE 1)	2)	
18 THERAPY DATES(From/To) 1) 27/JUL/2018	2) 27/JUL/2018	19 THERAPY DURATION 1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER

MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO 2019-[redacted] (0)

24c DATE RECEIVED BY MANUFACTURER 29/MAY/2019

24d REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT 24/JUN/2021

25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	27/Jul/2018
Seq No	:	2
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	27/Jul/2018
Seq No	:	3
Reaction	:	TRÖTT (Tiredness)
Start Date	:	27/Jul/2018
Seq No	:	4
Reaction	:	RYCKER I BENEN (Muscle twitching)
Start Date	:	27/Jul/2018
Seq No	:	5
Reaction	:	MYRKRYPNINGAR (Formication)
Start Date	:	27/Jul/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

MYRKRYPNINGAR (Formication) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 15-årig flicka.
Rapporterat misstänkt läkemedel var Lergigan (promethazine), Propavan (propiomazine), sertraline.
Rapporterat som avsiktlig självdestruktiv handling, avsiktlig överdosering, trött, rycker i benen, myrkrypni
ngar.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 27/JUL/2018 - 27/JUL/2018
Seq No	:	2
Drug	:	Propavan(propiomazine maleate, propiomazine)(propiomazine maleate, propiomazine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 27/JUL/2018 - 27/JUL/2018
Seq No	:	3
Drug	:	sertraline(Sertraline)(Sertraline)
Daily Dose	:	1) (250 Milligram)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 27/JUL/2018 - 27/JUL/2018

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR
	SVERIGE				17	Kvinna	04	JUN	2018

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

SUICIDSYFTE (Suicidal intention) - Okänd
Protocol relatedness:
As per reporter:
As per company:

RLS 3 (Consciousness decreased) - Okänd
Protocol relatedness:
As per reporter:
As per company:

MYDRIASIS (Mydriasis) - Okänd
Protocol relatedness:

Cont...

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine
2) sertraline(Sertraline)(Sertraline)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) 2)	1) Per oral 2)	☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 04/JUN/2018 2) 04/JUN/2018	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER	24d REPORT SOURCE
29/MAY/2019	☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER
DATE OF THIS REPORT 24/JUN/2021	25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	04/Jun/2018
Seq No	:	2
Reaction	:	SUICIDSYFTE (Suicidal intention)
Start Date	:	04/Jun/2018
Seq No	:	3
Reaction	:	RLS 3 (Consciousness decreased)
Start Date	:	05/Jun/2018
Seq No	:	4
Reaction	:	MYDRIASIS (Mydriasis)
Start Date	:	05/Jun/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 17-årig flicka.

Rapporterat misstänkt läkemedel var okänd dos av Lergigan (promethazine), Propavan (propiomazine) och sertra line som hon har förskrivet sedan tidigare. "Ev har hon tagit tramadol tidigare." Cirka 2 veckor tidigare "fic k hon 100 lergigan, 100 sertralin, 50 propavan".
Inkommer till sjukhus ca 4 timmar efter intag. Rapporterat som avsiktlig överdosering i suicidsyfte. RLS 3, my driasis, cirkulatoriskt stabil. Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 04/JUN/2018 - 04/JUN/2018
Seq No	:	2
Drug	:	sertraline(Sertraline)(Sertraline)
Therapy Dates/Duration	:	1) 04/JUN/2018 - 04/JUN/2018
Seq No	:	3
Drug	:	Propavan(propiomazine maleate, propiomazine)(propiomazine maleate, propiomazine)
Therapy Dates/Duration	:	1) 04/JUN/2018 - 04/JUN/2018

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR
	SVERIGE				16	Kvinna	31	OCT	2018

7 +13 DESCRIBE REACTION(S) (include relevant tests/lab data)

SUICID (FÖRSÖK) (Suicide attempt) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

TORR I MUNNEN (Dry mouth) - Okänd
Protocol relatedness:
As per reporter:
As per company:

TAKYKARD (Tachycardia) - Okänd
Protocol relatedness:

Cont...

8 -12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Propavan(propiomazine maleate, propiomazine)(propiomazine maleate,
2) Theralen(alimemazine, alimemazine hemitartrate)(alimemazine,

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE
1) (500 Milligram) 2) "vet ej hur må-

16 ROUTE OF ADMINISTRATION
1) Per oral 2) Per oral

21 DID EVENT REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)
1) 31/OCT/2018 2) 31/OCT/2018

19 THERAPY DURATION
1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER

MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER
29/MAY/2019

24d REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
24/JUN/2021

25a REPORT TYPE
☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	SUICID (FÖRSÖK) (Suicide attempt)
Start Date	:	31/Oct/2018
Seq No	:	2
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	31/Oct/2018
Seq No	:	3
Reaction	:	TORR I MUNNEN (Dry mouth)
Start Date	:	31/Oct/2018
Seq No	:	4
Reaction	:	TAKYKARD (Tachycardia)
Start Date	:	31/Oct/2018
Seq No	:	5
Reaction	:	LAKTATSTEGRING (Lactate increased)
Start Date	:	31/Oct/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

LAKTATSTEGRING (Lactate increased) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 16-årig flicka.
Rapporterat misstänkt läkemedel var Elvanse (lisdexamfetamine), Propavan (propiomazine), Strattera (atomoxeti
ne), Theralen (alimemazine) samt "ev" även sertraline ("har ej tagit/osäker").
Rapporterat som avsiktlig överdosering, suicid (försök). Cirka 1,5 timme efter intag var flickan vaken, myck
et torr i munnen, stabil i vitalparametrar. Cirka 1,5 timme senare "rel opåverkad takykard 150/min, RLS 1". Ca
15 minuter senare "lite taykard. cirk stabil", "lite laktat 3-4. ingen kramp" (referensvärde saknas). Enligt G
iftinformationscentralen inte typiskt med laktatstegringm "läkare ska följa".
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Propavan(propiomazine maleate, propiomazine)(propiomazine maleate, propiomazine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 31/OCT/2018 - 31/OCT/2018
Seq No	:	2
Drug	:	Theralen(alimemazine, alimemazine hemitartrate)(alimemazine, alimemazine hemitartrate)
Daily Dose	:	1) "vet ej hur många", "125 mg"
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 31/OCT/2018 - 31/OCT/2018
Seq No	:	3
Drug	:	Strattera(atomoxetine hydrochloride, atomoxetine)(atomoxetine hydrochloride, atomoxetine)
Daily Dose	:	1) Oklar mängd
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 31/OCT/2018 - 31/OCT/2018
Seq No	:	4
Drug	:	Elvanse(lisdexamfetamine dimesilate, lisdexamfetamine, dexamfetamine)(lisdexamfetamine dimesilate, lisdexamfetamine, dexamfetamine)
Daily Dose	:	1) (300 Milligram)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 31/OCT/2018 - 31/OCT/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted] (0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR
	SVERIGE				19	Kvinna	03	JUN	2018

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 19-årig kvinna.
Rapporterat misstänkt läkemedel var 25 st Lergigan (promethazine) samt ev. tagi

Cont...

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) fluoxetine(Fluoxetine)(Fluoxetine)
2) Lergigan(promethazine, promethazine

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) 2) (625 Milligram)	1) 2) Per oral	☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 03/JUN/2018 2) 03/JUN/2018	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY
No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted] (0)

24c DATE RECEIVED BY MANUFACTURER	24d REPORT SOURCE
29/MAY/2019	☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER
DATE OF THIS REPORT 24/JUN/2021	25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No : 1
Reaction : AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date : 03/Jun/2018

Seq No : 2
Reaction : AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date : 03/Jun/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

t fluoxetine 20 mg. Rapporterat som avsiktlig överdosering, avsiktlig självdestruktiv handling.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No : 1
Drug : fluoxetine(Fluoxetine)(Fluoxetine)
Therapy Dates/Duration : 1) 03/JUN/2018 - 03/JUN/2018

Seq No : 2
Drug : Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Route of Admin : 1) Per oral
Therapy Dates/Duration : 1) 03/JUN/2018 - 03/JUN/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	2 DATE OF BIRTH MO	2 DATE OF BIRTH YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	4-6 REACTION ONSET MO	4-6 REACTION ONSET YR
	SVERIGE				16	Kvinna	11	APR	2018

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

TORR I MUNNEN (Dry mouth) - Okänd
Protocol relatedness:
As per reporter:
As per company:

FÖRVIRRAD (Confused) - Okänd
Protocol relatedness:

Cont...

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine
2) escitalopram(Escitalopram)(Escitalop-

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION
1) (2500 Milligra- 2) "tom karta"	1) Per oral 2) Per oral

21 DID EVENT REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 11/APR/2018 2) 11/APR/2018	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER	24d REPORT SOURCE
29/MAY/2019	☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER
DATE OF THIS REPORT: 24/JUN/2021	25a REPORT TYPE: ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed BMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	11/Apr/2018
Seq No	:	2
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	11/Apr/2018
Seq No	:	3
Reaction	:	TORR I MUNNEN (Dry mouth)
Start Date	:	11/Apr/2018
Seq No	:	4
Reaction	:	FÖRVIRRAD (Confused)
Start Date	:	11/Apr/2018
Seq No	:	5
Reaction	:	DESORIENTERAD (Disorientation)
Start Date	:	11/Apr/2018
Seq No	:	6
Reaction	:	SKAKIG (Shakiness)
Start Date	:	11/Apr/2018
Seq No	:	7
Reaction	:	FÖRLÅNGD QTC (Electrocardiogram QTc interval prolonged)
Start Date	:	11/Apr/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

DESORIENTERAD (Disorientation) - Okänd
Protocol relatedness:
As per reporter:
As per company:

SKAKIG (Shakiness) - Okänd
Protocol relatedness:
As per reporter:
As per company:

FÖRLÅNGD QTC (Electrocardiogram QTc interval prolonged) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 16-årig flicka.

Rapporterat misstänkt läkemedel var 2500 mg Lergigan (promethazine) och "tom karta" escitalopram för "en vec
kas förbrukning".
Oklart när läkemedlen intogs. Rapporterat som avsiktlig självdestruktiv handling, avsiktlig överdosering. H
on är torr i munnen, "plockig", förvirrad, desorienterad, skakig, lite förlängd QTc 586. 128 i puls, 145/10
0 i blodtryck som senare sjunker till 127/89. Får kol i ambulansen. Cirk. stabil, bra blodgaser.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Daily Dose	:	1) (2500 Milligram)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 11/APR/2018 - 11/APR/2018
Seq No	:	2
Drug	:	escitalopram(Escitalopram)(Escitalopram)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 11/APR/2018 - 11/APR/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				17	Kvinna	22	OCT	2018	

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

SOMNOLENT (Somnolence) - Okänd
Protocol relatedness:
As per reporter:
As per company:

LITE HÖGT BLODTRYCK (Hypertension) - Okänd
Protocol relatedness:

Cont...

☐ PATIENT DIED
☐ LIFE THREATENING
☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
☐ CONGENITAL ANOMALY
☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine
2) Panodil(paracetamol)(paracetamol)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) 2) (1 Gram)	1) Per oral 2)	☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 22/OCT/2018 2) 22/OCT/2018	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER	24d REPORT SOURCE
29/MAY/2019	☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER
DATE OF THIS REPORT 24/JUN/2021	25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	22/Oct/2018
Seq No	:	2
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	22/Oct/2018
Seq No	:	3
Reaction	:	SOMNOLENT (Somnolence)
Start Date	:	23/Oct/2018
Seq No	:	4
Reaction	:	LITE HÖGT BLODTRYCK (Hypertension)
Start Date	:	23/Oct/2018
Seq No	:	5
Reaction	:	LITE ONT I MAGEN (Abdominal pain)
Start Date	:	23/Oct/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

LITE ONT I MAGEN (Abdominal pain) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 17-årig flicka med panikångest.
Rapporterat misstänkt läkemedel var Lergigan (promethazine), Panodil (paracetamol), fluoxetine, ibuprofen. Rapporterat som avsiktlig överdosering, avsiktlig
självdestruktiv handling, somnolent, lite högt blodtryck, lite ont i magen. Oklart hur mycket Lergigan flicka n tagit "en handfull mängd"
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 22/OCT/2018 - 22/OCT/2018
Seq No	:	2
Drug	:	Panodil(paracetamol)(paracetamol)
Therapy Dates/Duration	:	1) 22/OCT/2018 - 22/OCT/2018
Seq No	:	3
Drug	:	ibuprofen(Ibuprofen)(Ibuprofen)
Daily Dose	:	1) (2400 Milligram)
Therapy Dates/Duration	:	1) 22/OCT/2018 - 22/OCT/2018
Seq No	:	4
Drug	:	fluoxetine(Fluoxetine)(Fluoxetine)
Daily Dose	:	1) "medicinerar vanligtvis 20 mg saknas 8 st"
Therapy Dates/Duration	:	1) 22/OCT/2018 - 22/OCT/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted] (0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				13	Kvinna	25	AUG	2018	

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 13-årig flicka.
Rapporterat misstänkt läkemedel var Atarax (hydroxyzine), Lergigan comp. (prome

Cont...

☐ PATIENT DIED
☐ LIFE THREATENING
☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
☐ CONGENITAL ANOMALY
☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan comp.(ephedrine sulfate, promethazine, caffeine, promethazine
2) Ritalin(methylphenidate hydrochloride,

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE
1) 20 st lergigan,- 2) 21 tabletter

16 ROUTE OF ADMINISTRATION
1) Per oral 2)

21 DID EVENT REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)
1) 25/AUG/2018 2) 25/AUG/2018

19 THERAPY DURATION
1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY
No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted] (0)

24c DATE RECEIVED BY MANUFACTURER
29/MAY/2019

24d REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
24/JUN/2021

25a REPORT TYPE
☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	25/Aug/2018
Seq No	:	2
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	25/Aug/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

thazine, combinations), Ritalin (methylphenidate). Har tagit Atarax 10 mg 14 tabletter, 140 mg samt 20 st lergigan, 10 mg comp (200 m lergigan, 100 mg koffein, 200 mg efedrin) samt Ritalin 30 mg 21 tab, totalt 630 mg.
Rapporterat som avsiktlig överdosering, avsiktlig självdestruktiv handling. Uppmanas att ge kol.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan comp.(ephedrine sulfate, promethazine, caffeine, promethazine hydrochloride, ephedrine (anhydrous))(ephedrine sulfate, promethazine, caffeine, promethazine hydrochloride, ephedrine (anhydrous))
Daily Dose	:	1) 20 st lergigan, 10 mg comp 200 mg lergigan 1000 mg koffein 200mg efedrin
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 25/AUG/2018 - 25/AUG/2018
Seq No	:	2
Drug	:	Ritalin(methylphenidate hydrochloride, methylphenidate)(methylphenidate hydrochloride, methylphenidate)
Daily Dose	:	1) 21 tabletter 630 mg
Therapy Dates/Duration	:	1) 25/AUG/2018 - 25/AUG/2018
Seq No	:	3
Drug	:	Atarax(hydroxyzine hydrochloride, hydroxyzine)(hydroxyzine hydrochloride, hydroxyzine)
Daily Dose	:	1) 14 tabl 140 mg
Therapy Dates/Duration	:	1) 25/AUG/2018 - 25/AUG/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				15	Kvinna	16	MAY	2019	

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

SÖMNIG (Sleepiness) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

Cont...

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Propavan(propiomazine maleate, propiomazine)(propiomazine maleate,
2) Atarax(hydroxyzine hydrochloride, hydroxyzine)(hydroxyzine

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) (600 Milligram) 2) (425 Milligram)	1) Per oral 2) Per oral	☐ YES ☐ NO ☐ NA
17 INDICATIONS FOR USE 1)	2)	
18 THERAPY DATES(From/To) 1) 16/MAY/2019	2) 16/MAY/2019	19 THERAPY DURATION 1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER

MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO 2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER 29/MAY/2019

24d REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT 24/JUN/2021

25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	16/May/2019
Seq No	:	2
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	16/May/2019
Seq No	:	3
Reaction	:	SÖMNIG (Sleepiness)
Start Date	:	16/May/2019

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 15-årig flicka.
Rapporterat misstänkt läkemedel var Atarax (hydroxyzine), Propavan (propiomazine), fluoxetine. Rapporterat so
m avsiktlig självdestruktiv handling, avsiktlig
överdosering, sömnig. Ur rapport "parametrar ok"
Rapport daterad ca 3 timmar efter intag.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Propavan(propiomazine maleate, propiomazine)(propiomazine maleate, propiomazine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 16/MAY/2019 - 16/MAY/2019
Seq No	:	2
Drug	:	Atarax(hydroxyzine hydrochloride, hydroxyzine)(hydroxyzine hydrochloride, hydroxyzine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 16/MAY/2019 - 16/MAY/2019
Seq No	:	3
Drug	:	fluoxetine(Fluoxetine)(Fluoxetine)
Daily Dose	:	1) (130 Milligram)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 16/MAY/2019 - 16/MAY/2019

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted] (0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR
	SVERIGE				14	Kvinna	17	JUN	2019

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 14-årig flicka.
Rapporterat misstänkt läkemedel var Lergigan (promethazine), sertraline. Rappor

Cont...

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine
2) sertraline(Sertraline)(Sertraline)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION
1) (700 Milligram) 2) (3 Gram)	1) Per oral 2) Per oral

21 DID EVENT REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 17/JUN/2019 2) 17/JUN/2019	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER

MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO 2019-[redacted] (0)

24c DATE RECEIVED BY MANUFACTURER 03/AUG/2019

24d REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT 24/JUN/2021

25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	17/Jun/2019
Seq No	:	2
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	17/Jun/2019

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

terat som avsiktlig överdosering, avsiktlig självdestruktiv handling. Knappt två timmar efter intag beskrivs flickan som "ej orolig, ej aggressiv, vaken pratbar". Hon hade fått behandling med kol.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 17/JUN/2019 - 17/JUN/2019
Seq No	:	2
Drug	:	sertraline(Sertraline)(Sertraline)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 17/JUN/2019 - 17/JUN/2019

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				19	Kvinna	05	FEB	2019	

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

TAKYKARD (Tachycardia) - Okänd
Protocol relatedness:
As per reporter:
As per company:

MOTORISKT NÅGOT OROLIG (Motor restlessness) - Okänd
Protocol relatedness:

Cont...

☐ PATIENT DIED
☐ LIFE THREATENING
☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
☐ CONGENITAL ANOMALY
☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine
2) buspirone(Buspirone)(Buspirone)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) (500 Milligram) 2)	1) Per oral 2) Per oral	☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 05/FEB/2019 2) 05/FEB/2019	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER	24d REPORT SOURCE
29/MAY/2019	☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER
DATE OF THIS REPORT 24/JUN/2021	25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	05/Feb/2019
Seq No	:	2
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	05/Feb/2019
Seq No	:	3
Reaction	:	TAKYKARD (Tachycardia)
Start Date	:	05/Feb/2019
Seq No	:	4
Reaction	:	MOTORISKT NÅGOT OROLIG (Motor restlessness)
Start Date	:	05/Feb/2019
Seq No	:	5
Reaction	:	SMÅ PUPILLER (Constricted pupils)
Start Date	:	05/Feb/2019

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

SMÅ PUPILLER (Constricted pupils) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 19-årig kvinna.
Rapporterat misstänkt läkemedel var Anafranil (clomipramine), Zyprexa (olanzapine), buspirone som kvinnan tag
it oklar mängd av, kräktes direkt upp "i princip samtliga tabletter." Tog sedan Lergigan (promethazine) 2
5 mg 20 st,
Rapporterat som avsiktlig överdosering, avsiktlig självdestruktiv handling, takykard 115/min, motoriskt någ
t orolig, små pupiller. S-kalcium 1,06 (Ref. 2,15-2,50), "QRS 92; QTc 476"
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.
Ref. enligt NORIP/Equalis.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 05/FEB/2019 - 05/FEB/2019
Seq No	:	2
Drug	:	buspirone(Buspirone)(Buspirone)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 05/FEB/2019 - 05/FEB/2019
Seq No	:	3
Drug	:	Anafranil(clomipramine hydrochloride, clomipramine)(clomipramine hydrochloride, clomipramine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 05/FEB/2019 - 05/FEB/2019
Seq No	:	4
Drug	:	Zyprexa(olanzapine)(olanzapine)
Therapy Dates/Duration	:	1) 05/FEB/2019 - 05/FEB/2019

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				14	Kvinna	31	JUL	2018	

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

KONFUSORISK, PLOCKIG (Confusion) - Okänd
Protocol relatedness:
As per reporter:
As per company:

HALLUCINERAR (Hallucinating) - Okänd
Protocol relatedness:

Cont...

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine

2) Elvanse(lisdexamfetamine dimesilate, lisdexamfetamine,

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION
1) (1.25 Gram) 2) (1 Gram)	1) Per oral 2) Per oral

21 DID EVENT REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE	
1)	2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 31/JUL/2018 2) 31/JUL/2018	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER

MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR. CONTROL NO 2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER	24d REPORT SOURCE
29/MAY/2019	☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER
DATE OF THIS REPORT 24/JUN/2021	25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	31/Jul/2018
Seq No	:	2
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	31/Jul/2018
Seq No	:	3
Reaction	:	KONFUSORISK, PLOCKIG (Confusion)
Start Date	:	01/Aug/2018
Seq No	:	4
Reaction	:	HALLUCINERAR (Hallucinating)
Start Date	:	01/Aug/2018
Seq No	:	5
Reaction	:	TAKYKARD (Tachycardia)
Start Date	:	01/Aug/2018
Seq No	:	6
Reaction	:	OROLIG (Anxiety)
Start Date	:	01/Aug/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

TAKYKARD (Tachycardia) - Okänd
Protocol relatedness:
As per reporter:
As per company:

OROLIG (Anxiety) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 14-årig flicka.
Rapporterat misstänkt läkemedel var Elvanse (lisdexamfetamine), Lergigan (promethazine), Theralen (alimemazine) samt "ev sertralin50 mg 50 st".
Rapporterat som avsiktlig självdestruktiv handling, avsiktlig överdosering, konfusorisk, plockig, hallucinerar, takykard, orolig.
Enligt rapport fått fysostigmin gånger flera med god effekt men faller tillbaka till sina symtom som plockig, takykard hallucinationer, förvirrad.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 31/JUL/2018 - 31/JUL/2018
Seq No	:	2
Drug	:	Elvanse(lisdexamfetamine dimesilate, lisdexamfetamine, dexamfetamine)(lisdexamfetamine dimesilate, lisdexamfetamine, dexamfetamine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 31/JUL/2018 - 31/JUL/2018
Seq No	:	3
Drug	:	Theralen(alimemazine, alimemazine hemitartrate)(alimemazine, alimemazine hemitartrate)
Daily Dose	:	1) (150 Milligram)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 31/JUL/2018 - 31/JUL/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR
	SVERIGE				17	Kvinna	08	JUL	2019

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

SNABB I PULS (Pulse rapid) - Okänd
Protocol relatedness:
As per reporter:
As per company:

MYRKRYPNINGAR (Formication) - Okänd
Protocol relatedness:

Cont...

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Propavan(propiomazine maleate, propiomazine)(propiomazine maleate,
2) quetiapine(Quetiapine)(Quetiapine)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	17 INDICATIONS FOR USE	18 THERAPY DATES(From/To)	19 THERAPY DURATION
1)	1) Per oral	1)	1) 08/JUL/2019	1)
2)	2) Per oral	2)	2) 08/JUL/2019	2)

21 DID EVENT REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER

MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO 2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER 03/AUG/2019

24d REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT 24/JUN/2021

25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	08/Jul/2019
Seq No	:	2
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	08/Jul/2019
Seq No	:	3
Reaction	:	SNABB I PULS (Pulse rapid)
Start Date	:	08/Jul/2019
Seq No	:	4
Reaction	:	MYRKRYPNINGAR (Formication)
Start Date	:	08/Jul/2019
Seq No	:	5
Reaction	:	TRÖTT (Tiredness)
Start Date	:	08/Jul/2019

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

TRÖTT (Tiredness) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 17-årig flicka.
Rapporterat misstänkt läkemedel var Propavan (propiomazine), quetiapine, sertraline. Intagen dos av dessa fra
mkommer ej av rapport.
Rapporterat som avsiktlig självdestruktiv handling, avsiktlig överdosering, snabb i puls, myrkrypningar, tr
ött.
Nåt tidssamband framkommer ej av rapport.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Propavan(propiomazine maleate, propiomazine)(propiomazine maleate, propiomazine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 08/JUL/2019 - 08/JUL/2019
Seq No	:	2
Drug	:	quetiapine(Quetiapine)(Quetiapine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 08/JUL/2019 - 08/JUL/2019
Seq No	:	3
Drug	:	sertraline(Sertraline)(Sertraline)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 08/JUL/2019 - 08/JUL/2019

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				15	Kvinna	22	MAY	2018	

7 +13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

LITE TRÖTT (Tiredness) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

Cont...

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Propavan(propiomazine maleate, propiomazine)(propiomazine maleate,
2) Divisun(cholecalciferol, Dry Vitamin D3 100 SD/S)(cholecalciferol,
Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE
1) 2 st (50 Millig- 2)

16 ROUTE OF ADMINISTRATION
1) Per oral 2) Per oral

21 DID EVENT REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)
1) 22/MAY/2018 2) 22/MAY/2018

19 THERAPY DURATION
1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER
29/MAY/2019

24d REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
24/JUN/2021

25a REPORT TYPE
☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	22/May/2018
Seq No	:	2
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	22/May/2018
Seq No	:	3
Reaction	:	LITE TRÖTT (Tiredness)
Start Date	:	22/May/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 15-årig flicka som "tagit lite olika tabletter" kl 18 på kvällen.
Rapporterat misstänkt läkemedel var Abilify (aripiprazole) "25 mg, 2-3 st antagligen 2", Divisun (colecalciferol) (dos ej angiven), Propavan (propiomazine) "2 st 25 mg, vanliga dos", lamotrigine 2-3 st 5 mg, sertraline 2-3 st 50 mg.
Vid sjukvårdens kontakt med Giftinformationscentralenca kl 23 framkommer att flickan är "lite trött."

Rapporterat som avsiktlig överdosering, avsiktlig självdestruktiv handling, lite trött.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Propavan(propiomazine maleate, propiomazine)(propiomazine maleate, propiomazine)
Daily Dose	:	1) 2 st (50 Milligram)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 22/MAY/2018 - 22/MAY/2018
Seq No	:	2
Drug	:	Divisun(cholecalciferol, Dry Vitamin D3 100 SD/S)(cholecalciferol, Dry Vitamin D3 100 SD/S)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 22/MAY/2018 - 22/MAY/2018
Seq No	:	3
Drug	:	lamotrigine(Lamotrigine)(Lamotrigine)
Daily Dose	:	1) 2-3 st
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 22/MAY/2018 - 22/MAY/2018
Seq No	:	4
Drug	:	Abilify(aripiprazole (anhydrous))(aripiprazole (anhydrous))
Daily Dose	:	1) "25 mg", "2-3 st antagligen 2"
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 22/MAY/2018 - 22/MAY/2018
Seq No	:	5
Drug	:	sertraline(Sertraline)(Sertraline)
Daily Dose	:	1) "2-3"
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 22/MAY/2018 - 22/MAY/2018

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted] (0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				17	Kvinna	03	MAR	2019	

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 17-årig flicka.
Rapporterat misstänkta läkemedel var Alvedon (paracetamol), Atarax (hydroxyzine

Cont...

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine
2) Propavan(propiomazine maleate, propiomazine)(propiomazine maleate,

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) (1 in 1 En gå- 2) (1 in 1 En gå-	1) Per oral 2)	☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 03/MAR/2019 2) 03/MAR/2019	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted] (0)

24c DATE RECEIVED BY MANUFACTURER	24d REPORT SOURCE
29/MAY/2019	☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER
DATE OF THIS REPORT 24/JUN/2021	25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	03/Mar/2019
Seq No	:	2
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	03/Mar/2019

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

), Ipren (ibuprofen), Lergigan (promethazine), Propavan (propiomazine), mirtazapine. Läkemedlen hade tagits p
å natten till 2019-03-03, Alvedon 500 mg 5-10 st och Ipren 400 mg, mängden saknas för de andra läkemedlen.
När flickan väcktes på morgonen var hon rödmosig och trött. På sjukhuset togs prov för s-paracetamol, ho
n hade inga antikolinerga symtom och mådde ganska bra.
Rapporterat som avsiktlig överdosering, avsiktlig självdestruktiv handling.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Daily Dose	:	1) (1 in 1 En gång)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 03/MAR/2019 - 03/MAR/2019
Seq No	:	2
Drug	:	Propavan(propiomazine maleate, propiomazine)(propiomazine maleate, propiomazine)
Daily Dose	:	1) (1 in 1 En gång)
Therapy Dates/Duration	:	1) 03/MAR/2019 - 03/MAR/2019
Seq No	:	3
Drug	:	Atarax(hydroxyzine hydrochloride, hydroxyzine)(hydroxyzine hydrochloride, hydroxyzine)
Daily Dose	:	1) (1 in 1 En gång)
Therapy Dates/Duration	:	1) 03/MAR/2019 - 03/MAR/2019
Seq No	:	4
Drug	:	mirtazapine(Mirtazapine)(Mirtazapine)
Daily Dose	:	1) (1 in 1 En gång)
Therapy Dates/Duration	:	1) 03/MAR/2019 - 03/MAR/2019
Seq No	:	5
Drug	:	Alvedon(paracetamol)(paracetamol)
Daily Dose	:	1) 5-10 st (1 in 1 En gång)
Therapy Dates/Duration	:	1) 03/MAR/2019 - 03/MAR/2019
Seq No	:	6
Drug	:	Ipren(ibuprofen, Ibuprofen DC 85)(ibuprofen, Ibuprofen DC 85)
Daily Dose	:	1) 400 Milligram (400 Milligram,1 in 1 En gång)
Therapy Dates/Duration	:	1) 03/MAR/2019 -

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				19	Kvinna	20	MAR	2018	

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

SUICIDSYFTE (Suicidal intention) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

RLS 5 (Unconscious) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

Cont...

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine

2) CYMBALTA(duloxetine, duloxetine hydrochloride)(duloxetine, duloxetine

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) (2 Gram) 2) (600 Milligram)	1) Per oral 2) Per oral	☐ YES ☐ NO ☐ NA
17 INDICATIONS FOR USE 1) 2)		
18 THERAPY DATES(From/To) 1) 20/MAR/2018 2) 20/MAR/2018	19 THERAPY DURATION 1) 2)	

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER

MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO 2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER 29/MAY/2019

24d REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT 24/JUN/2021

25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	SUICIDSYFTE (Suicidal intention)
Start Date	:	20/Mar/2018
Seq No	:	2
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	20/Mar/2018
Seq No	:	3
Reaction	:	RLS 5 (Unconscious)
Start Date	:	20/Mar/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 19-årig kvinna.

Rapporterat misstänkt läkemedel var 600 mg CYMBALTA (duloxetine), 2 g Lergigan (promethazine). Rapporterat so
m suicidsyfte, avsiktlig överdosering, RLS 5, "cirk och resp stabil".
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 20/MAR/2018 - 20/MAR/2018
Seq No	:	2
Drug	:	CYMBALTA(duloxetine, duloxetine hydrochloride)(duloxetine, duloxetine hydrochloride)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 20/MAR/2018 - 20/MAR/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				17	Kvinna		JAN	2018	

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

MINNESFÖRLUST (Memory loss) - Okänd
Protocol relatedness:
As per reporter:
As per company:

KUNDE EJ GÅ OCH STÅ (Unable to walk) - Okänd
Protocol relatedness:

Cont...

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine
2) sertraline(Sertraline)(Sertraline)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION
1) (425 Milligram) 2) (1000 Milligra-	1) Per oral 2) Per oral

21 DID EVENT REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 09/JAN/2018 2) 10/JAN/2018	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER	24d REPORT SOURCE
29/MAY/2019	☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER
DATE OF THIS REPORT 24/JUN/2021	25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	09/Jan/2018
Seq No	:	2
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	09/Jan/2018
Seq No	:	3
Reaction	:	MINNESFÖRLUST (Memory loss)
Start Date	:	09/Jan/2018
Seq No	:	4
Reaction	:	KUNDE EJ GÅ OCH STÅ (Unable to walk)
Start Date	:	09/Jan/2018
Seq No	:	5
Reaction	:	STORA PUPILLER (Dilated pupils)
Start Date	:	10/Jan/2018
Seq No	:	6
Reaction	:	HJÄRTKLAPPNING (Heart pounding)
Start Date	:	10/Jan/2018
Seq No	:	7
Reaction	:	ÅNGESTLADDAD (Anxiety)
Start Date	:	/Jan/2018
Seq No	:	8
Reaction	:	SKAKIG (Shakiness)
Start Date	:	/Jan/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

STORA PUPILLER (Dilated pupils) - Okänd
Protocol relatedness:
As per reporter:
As per company:

HJÄRTKLAPPNING (Heart pounding) - Okänd
Protocol relatedness:
As per reporter:
As per company:

ÅNGESTLADDAD (Anxiety) - Okänd
Protocol relatedness:
As per reporter:
As per company:

SKAKIG (Shakiness) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 17-årig flicka.

Rapporterat misstänkt läkemedel var 425 mg Lergigan (promethazine) som intogs ena dagen. Efter dosen Lergigan fick hon minnesförlust, kunde inte gå eller stå. Sov under natten. På kvällen nästa dag tar hon 1000 mg s ertraline och får stora pupiller och lite hjärtklappning.

En vecka senare får sjukvården information om intaget och flickan berättar då att hon fortfarande känner s ig ostadig, ångestladdad och skakig.
Rapporterat som avsiktlig självdestruktiv handling, avsiktlig överdosering. Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 09/JAN/2018 - 09/JAN/2018
Seq No	:	2
Drug	:	sertraline(Sertraline)(Sertraline)
Daily Dose	:	1) (1000 Milligram)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 10/JAN/2018 - 10/JAN/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	2 DATE OF BIRTH MO	2 DATE OF BIRTH YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	4-6 REACTION ONSET MO	4-6 REACTION ONSET YR
	SVERIGE				13	Kvinna	14	JUN	2019

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

FÖRVIRRAD (Confused) - Okänd
Protocol relatedness:
As per reporter:
As per company:

SOMNOLENT (Somnolence) - Okänd
Protocol relatedness:

Cont...

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Propavan(propiomazine maleate, propiomazine)(propiomazine maleate,
2) sertraline(Sertraline)(Sertraline)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE
1)
2) "100 mg"

16 ROUTE OF ADMINISTRATION
1) Per oral
2)

21 DID EVENT REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1)
2)

18 THERAPY DATES(From/To)
1) 14/JUN/2019
2) 14/JUN/2019

19 THERAPY DURATION
1)
2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER

MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER
03/AUG/2019

24d REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
24/JUN/2021

25a REPORT TYPE
☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	14/Jun/2019
Seq No	:	2
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	14/Jun/2019
Seq No	:	3
Reaction	:	FÖRVIRRAD (Confused)
Start Date	:	14/Jun/2019
Seq No	:	4
Reaction	:	SOMNOLENT (Somnolence)
Start Date	:	14/Jun/2019
Seq No	:	5
Reaction	:	SMÅ PUPILLER (Constricted pupils)
Start Date	:	14/Jun/2019

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

SMÅ PUPILLER (Constricted pupils) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 13-årig flicka.
Rapporterat misstänkt läkemedel var Propavan (propiomazine), paracetamol och sertralin. Rapporterat som avsiktlig självdestruktiv handling,
avsiktlig överdosering. "Trol ej stora mängder men oklart". Tidpunkt för intag är osäker "kanske kl 13".
Läkare på sjukhus kontaktar Giftinformationscentralen kl 19:31.
"förvirrad och somnolent när hon kom in, men piggare nu", "kissat ner sig tidigare, ev krampat", "lite små pupiller"
Svar på s-paracetamol har ännu inte kommit. Giftinformationscentralen rekommenderar övervakning av medvetandegrad, puls, blodtryck och andning samt diagnostiskt EKG.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Propavan(propiomazine maleate, propiomazine)(propiomazine maleate, propiomazine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 14/JUN/2019 - 14/JUN/2019
Seq No	:	2
Drug	:	sertraline(Sertraline)(Sertraline)
Therapy Dates/Duration	:	1) 14/JUN/2019 - 14/JUN/2019
Seq No	:	3
Drug	:	paracetamol(Paracetamol)(Paracetamol)
Therapy Dates/Duration	:	1) 14/JUN/2019 - 14/JUN/2019

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted] (0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR
	SVERIGE				15	Kvinna	06	JUN	2018

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 15-årig flicka.
Rapporterat misstänkt läkemedel var Propavan (propiomazine), fluoxetine, melato

Cont...

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Propavan(propiomazine maleate, propiomazine)(propiomazine maleate,
2) fluoxetine(Fluoxetine)(Fluoxetine)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) 2)	1) Per oral 2) Per oral	☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 06/JUN/2018 2) 06/JUN/2018	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted] (0)

24c DATE RECEIVED BY MANUFACTURER
29/MAY/2019

24d REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
24/JUN/2021

25a REPORT TYPE
☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	06/Jun/2018
Seq No	:	2
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	06/Jun/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

nin. Intagen mängd 30 st men framkommer "vet ej ngt om fördelning".
Rapporterat som avsiktlig självdestruktiv handling, avsiktlig överdosering.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Propavan(propiomazine maleate, propiomazine)(propiomazine maleate, propiomazine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 06/JUN/2018 - 06/JUN/2018
Seq No	:	2
Drug	:	fluoxetine(Fluoxetine)(Fluoxetine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 06/JUN/2018 - 06/JUN/2018
Seq No	:	3
Drug	:	melatonin(Melatonin)(Melatonin)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 06/JUN/2018 - 06/JUN/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted] (0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR
	SVERIGE				19	Man	20	MAY	2018

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

DÅSIG (Drowsiness) - Okänd
Protocol relatedness:
As per reporter:
As per company:

TAKYKARDI (Tachycardia) - Okänd
Protocol relatedness:

Cont...

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Propavan(propiomazine maleate, propiomazine)(propiomazine maleate,

2) Theralen(alimemazine, alimemazine hemitartrate)(alimemazine,

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION
1) 20 st 2) "lite"	1) Per oral 2) Per oral

21 DID EVENT REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 20/MAY/2018 2) 20/MAY/2018	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted] (0)

24c DATE RECEIVED BY MANUFACTURER
29/MAY/2019

24d REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
24/JUN/2021

25a REPORT TYPE
☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	20/May/2018
Seq No	:	2
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	20/May/2018
Seq No	:	3
Reaction	:	DÅSIG (Drowsiness)
Start Date	:	21/May/2018
Seq No	:	4
Reaction	:	TAKYKARDI (Tachycardia)
Start Date	:	21/May/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 19-årig man.
Rapporterat misstänkt läkemedel var Lergigan (promethazine), Propavan (propiomazine), Theralen (alimemazine) och sertraline. Rapporterat som avsiktlig
självdestruktiv handling, avsiktlig överdosering. När läkare på sjukhus kontaktar Giftinformationscentrale
n ca 15 timmar efter intaget är mannen dåsig och har takykardi 114/min. Giftinformationscentralen rekommender
ar fortsatt observation och symtomatisk behandling.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Propavan(propiomazine maleate, propiomazine)(propiomazine maleate, propiomazine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 20/MAY/2018 - 20/MAY/2018
Seq No	:	2
Drug	:	Theralen(alimemazine, alimemazine hemitartrate)(alimemazine, alimemazine hemitartrate)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 20/MAY/2018 - 20/MAY/2018
Seq No	:	3
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Daily Dose	:	1) mängd framgår inte
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 20/MAY/2018 - 20/MAY/2018
Seq No	:	4
Drug	:	sertraline(Sertraline)(Sertraline)
Daily Dose	:	1) 15 st á 50 mg (750 Milligram)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 20/MAY/2018 - 20/MAY/2018

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4 -6 REACTION ONSET DA	MO	YR
	SVERIGE				15	Kvinna	09	APR	2018

8 -12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

7 +13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

LITE YR (Dizzy) - Okänd
Protocol relatedness:
As per reporter:
As per company:

LITE TRÖTT (Tiredness) - Okänd
Protocol relatedness:

Cont...

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine
2) Propavan(propiomazine maleate, propiomazine)(propiomazine maleate,

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) (100 Milligram) 2) (100 Milligram)	1) Per oral 2) Per oral	☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 09/APR/2018 2) 09/APR/2018	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY
No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER
29/MAY/2019

24d REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
24/JUN/2021

25a REPORT TYPE
☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	09/Apr/2018
Seq No	:	2
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	09/Apr/2018
Seq No	:	3
Reaction	:	LITE YR (Dizzy)
Start Date	:	09/Apr/2018
Seq No	:	4
Reaction	:	LITE TRÖTT (Tiredness)
Start Date	:	09/Apr/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 15-årig flicka.
Rapporterat misstänkt läkemedel var Circadin (melatonin), Lergigan (promethazine), Propavan (propiomazine), f
luoxetine. Rapporterat som avsiktlig överdosering,
avsiktlig självdestruktiv handling. En timme efter intag beskrivs flickan som lite yr och lite trött. "97 i p
uls".
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 09/APR/2018 - 09/APR/2018
Seq No	:	2
Drug	:	Propavan(propiomazine maleate, propiomazine)(propiomazine maleate, propiomazine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 09/APR/2018 - 09/APR/2018
Seq No	:	3
Drug	:	Circadin(melatonin)(melatonin)
Daily Dose	:	1) (8 Milligram)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 09/APR/2018 - 09/APR/2018
Seq No	:	4
Drug	:	fluoxetine(Fluoxetine)(Fluoxetine)
Daily Dose	:	1) (100 Milligram)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 09/APR/2018 - 09/APR/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				18	Kvinna	15	MAR	2018	

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

TAKYKARD (Tachycardia) - Okänd
Protocol relatedness:
As per reporter:
As per company:

MOTORISKT OROLIG (Motor restlessness) - Okänd
Protocol relatedness:

Cont...

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Propavan(propiomazine maleate, propiomazine)(propiomazine maleate,
2) Atarax(hydroxyzine hydrochloride, hydroxyzine)(hydroxyzine

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE
1) (300 Milligram) 2) (1.5 Gram)

16 ROUTE OF ADMINISTRATION
1) Per oral 2)

21 DID EVENT REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)
1) 15/MAR/2018 2) 15/MAR/2018

19 THERAPY DURATION
1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER
29/MAY/2019

24d REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
24/JUN/2021

25a REPORT TYPE
☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	15/Mar/2018
Seq No	:	2
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	15/Mar/2018
Seq No	:	3
Reaction	:	TAKYKARD (Tachycardia)
Start Date	:	15/Mar/2018
Seq No	:	4
Reaction	:	MOTORISKT OROLIG (Motor restlessness)
Start Date	:	15/Mar/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 18-årig kvinna.
Rapporterat misstänkt läkemedel var Atarax (hydroxyzine), Propavan (propiomazine) och fluoxetine. Rapporterat som avsiktlig självdestruktiv handling, avsiktlig
överdosering. Intaget skedde kl 17.
Vid kontakt med Giftinformationscentralen kl 20:38 är kvinnan vaken, lite takykard och motoriskt orolig.
"qtc 590", "fått kol i ambulansen"
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Propavan(propiomazine maleate, propiomazine)(propiomazine maleate, propiomazine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 15/MAR/2018 - 15/MAR/2018
Seq No	:	2
Drug	:	Atarax(hydroxyzine hydrochloride, hydroxyzine)(hydroxyzine hydrochloride, hydroxyzine)
Therapy Dates/Duration	:	1) 15/MAR/2018 - 15/MAR/2018
Seq No	:	3
Drug	:	fluoxetine(Fluoxetine)(Fluoxetine)
Daily Dose	:	1) "oklar mängd men inte så många"
Therapy Dates/Duration	:	1) 15/MAR/2018 - 15/MAR/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				16	Kvinna	28	MAY	2018	

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

TRÖTT (Tiredness) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

Cont...

☐ PATIENT DIED
☐ LIFE THREATENING
☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
☐ CONGENITAL ANOMALY
☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Propavan(propiomazine maleate, propiomazine)(propiomazine maleate,
2) citalopram(Citalopram)(Citalopram)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) (175 Milligram) 2) (90 Milligram)	1) Per oral 2) Per oral	☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE	
1)	2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 28/MAY/2018 2) 28/MAY/2018	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER

MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO 2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER 29/MAY/2019

24d REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT 24/JUN/2021

25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	28/May/2018
Seq No	:	2
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	28/May/2018
Seq No	:	3
Reaction	:	TRÖTT (Tiredness)
Start Date	:	29/May/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 16-årig flicka.
Rapporterat misstänkt läkemedel var 175 mg Propavan (propiomazine), 90 mg citalopram, okänd mängd melatonin
.
Rapporterat som avsiktlig självdestruktiv handling, avsiktlig överdosering, trött. Rapport daterad ca 7 timm
ar efter intag.
Kvinnan opåverkad.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Propavan(propiomazine maleate, propiomazine)(propiomazine maleate, propiomazine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 28/MAY/2018 - 28/MAY/2018
Seq No	:	2
Drug	:	citalopram(Citalopram)(Citalopram)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 28/MAY/2018 - 28/MAY/2018
Seq No	:	3
Drug	:	melatonin(Melatonin)(Melatonin)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 28/MAY/2018 - 28/MAY/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR
	SVERIGE				17	Kvinna	08	APR	2018

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

KRÄKTES (Vomited) - Okänd
Protocol relatedness:
As per reporter:
As per company:

TRÖTT (Tiredness) - Okänd
Protocol relatedness:

Cont...

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine
2) melatonin(Melatonin)(Melatonin)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION
1) (150 Milligram) 2) "ca 45 mg"	1) Per oral 2) Per oral

21 DID EVENT REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 08/APR/2018 2) 08/APR/2018	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER

MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER	24d REPORT SOURCE
29/MAY/2019	☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER
DATE OF THIS REPORT: 24/JUN/2021	25a REPORT TYPE: ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	08/Apr/2018
Seq No	:	2
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	08/Apr/2018
Seq No	:	3
Reaction	:	KRÄKTES (Vomited)
Start Date	:	08/Apr/2018
Seq No	:	4
Reaction	:	TRÖTT (Tiredness)
Start Date	:	08/Apr/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 17-årig flicka. Den medicinska historien inkluderade ång
est, depression.
Rapporterat misstänkt läkemedel var Lergigan (promethazine), melatonin, sertraline. Rapporterat som avsiktlig
överdosering, avsiktlig självdestruktiv handling. Flickan kräktes 1-2 timmar efter intag. "trött initialt".
Vid kontakt med Giftinformationscentralen står det att kvinnan inkom (till sjukhus) 10 timmar efter intag. "pi
gg och mår bra", "inget på EKG och inget på prover".
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 08/APR/2018 - 08/APR/2018
Seq No	:	2
Drug	:	melatonin(Melatonin)(Melatonin)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 08/APR/2018 - 08/APR/2018
Seq No	:	3
Drug	:	sertraline(Sertraline)(Sertraline)
Daily Dose	:	1) (75 Milligram)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 08/APR/2018 - 08/APR/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				19	Kvinna	13	JUN	2018	

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

LITE SNABB I PULS, 108 (Pulse rapid) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

Cont...

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine
2) Propavan(propiomazine maleate, propiomazine)(propiomazine maleate,

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE
1) (375 Milligram) 2) "5 st propavan"

16 ROUTE OF ADMINISTRATION
1) Per oral 2) Per oral

21 DID EVENT REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)
1) 13/JUN/2018 2) 13/JUN/2018

19 THERAPY DURATION
1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER
29/MAY/2019

24d REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
24/JUN/2021

25a REPORT TYPE
☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	13/Jun/2018
Seq No	:	2
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	13/Jun/2018
Seq No	:	3
Reaction	:	LITE SNABB I PULS, 108 (Pulse rapid)
Start Date	:	13/Jun/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 19-årig kvinna.
Rapporterat misstänkt läkemedel var Lergigan (promethazine), Propavan (propiomazine), venlafaxine. Rapportera
t som avsiktlig självdestruktiv handling, avsiktlig
överdosering, lite snabb i puls, 108.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 13/JUN/2018 - 13/JUN/2018
Seq No	:	2
Drug	:	Propavan(propiomazine maleate, propiomazine)(propiomazine maleate, propiomazine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 13/JUN/2018 - 13/JUN/2018
Seq No	:	3
Drug	:	venlafaxine(Venlafaxine)(Venlafaxine)
Daily Dose	:	1) (750 Milligram)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 13/JUN/2018 - 13/JUN/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				16	Kvinna	21	MAR	2019	

7 +13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

SUICIDFÖRSÖK (Suicide attempt) - Okänd
Protocol relatedness:
As per reporter:
As per company:

BLANDINTOX (Drug intoxication) - Okänd
Protocol relatedness:
As per reporter:
As per company:

TAKYKARD (Tachycardia) - Okänd
Protocol relatedness:

Cont...

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan 25 mg Filmdragerad tablett(Lergigan)(promethazine,
2) sertraline(Sertraline)(Sertraline)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) (2.5 Gram) 2) (5 Gram)	1) Per oral 2) Per oral	☐ YES ☐ NO ☐ NA
17 INDICATIONS FOR USE 1) 2)		
18 THERAPY DATES(From/To) 1) 21/MAR/2019 2) 21/MAR/2019	19 THERAPY DURATION 1) 2)	

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER

MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO 2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER 29/MAY/2019

24d REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT 24/JUN/2021

25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA
Approval ID: 4171 Approval Date: 28/FEB/1953
(Lergigan 25 mg Filmdragerad tablett)

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	21/Mar/2019
Seq No	:	2
Reaction	:	SUICIDFÖRSÖK (Suicide attempt)
Start Date	:	21/Mar/2019
Seq No	:	3
Reaction	:	BLANDINTOX (Drug intoxication)
Start Date	:	21/Mar/2019
Seq No	:	4
Reaction	:	TAKYKARD (Tachycardia)
Start Date	:	21/Mar/2019
Seq No	:	5
Reaction	:	GCS 12-13 (Glasgow coma scale abnormal)
Start Date	:	21/Mar/2019
Seq No	:	6
Reaction	:	MOTORISKT OROLIG, PLOCKIG (Motor restlessness)
Start Date	:	21/Mar/2019
Seq No	:	7
Reaction	:	DARRIG (Tremor)
Start Date	:	21/Mar/2019
Seq No	:	8
Reaction	:	EKG-FÖRÄNDRING MED ST-SÄNKNING (ST depressed)
Start Date	:	21/Mar/2019
Seq No	:	9
Reaction	:	SOMNOLENT (Somnolence)
Start Date	:	21/Mar/2019
Seq No	:	10
Reaction	:	YR (Dizzy)
Start Date	:	21/Mar/2019

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

GCS 12-13 (Glasgow coma scale abnormal) - Okänd
Protocol relatedness:
As per reporter:
As per company:

MOTORISKT OROLIG, PLOCKIG (Motor restlessness) - Tillfrisknat utan men
Protocol relatedness:
As per reporter:
As per company:

DARRIG (Tremor) - Okänd
Protocol relatedness:
As per reporter:
As per company:

EKG-FÖRÄNDRING MED ST-SÄNKNING (ST depressed) - Okänd
Protocol relatedness:
As per reporter:
As per company:

SOMNOLENT (Somnolence) - Okänd
Protocol relatedness:
As per reporter:
As per company:

YR (Dizzy) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 16-årig flicka.
Rapporterat misstänkt läkemedel var Lamictal (lamotrigine), Lergigan (promethazine), Theralen (alimemazine), sertraline. Rapporterat som avsiktlig överdosering,
suicidförsök, blandintox. Flickan intog cannabis, alkohol och (enligt sista uppgiften till Giftinformationscentralen) "enstaka" Lamictal, 2,5 gram Lergigan, 500 mg Theralen och 5 gram sertraline. Flickan beskrivs initialt som takykard (puls 160), GSC 12-13 (Glasgow coma scale), motoriskt orolig och darrig. Blodgas visar normala elektrolyter, pCO2 och pH, laktat 3,3. Giftinformationscentralen rekommenderade kol. Vid ny kontakt med Giftinformationscentralen några timmar senare hade hon EKG-förändring med ST-sänkning som var takykardibetingad (sinustakykardi), var somnolent, yr och hade varit plockig, men vid samtalet "ej motoriskt orolig". Giftinformationscentralen rekommenderade fortsatt övervakning samt provtagning.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Seq No	:	1
Drug	:	Lergigan 25 mg Filmdragerad tablett(Lergigan)(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 21/MAR/2019 - 21/MAR/2019
Seq No	:	2
Drug	:	sertraline(Sertraline)(Sertraline)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 21/MAR/2019 - 21/MAR/2019
Seq No	:	3
Drug	:	Theralen(alimemazine, alimemazine hemitartrate)(alimemazine, alimemazine hemitartrate)
Daily Dose	:	1) (500 Milligram)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 21/MAR/2019 - 21/MAR/2019
Seq No	:	4
Drug	:	Lamictal(lamotrigine)(lamotrigine)
Daily Dose	:	1) "enstaka" "max 6 st"
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 21/MAR/2019 - 21/MAR/2019

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				17	Kvinna	17	JAN	2018	

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG ÖVERDOS (Overdose intentional) - Okänd
Protocol relatedness:
As per reporter:
As per company:

MEDVETSLÖS (Unconscious) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

Cont...

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine

2) Oralin(sertraline hydrochloride, sertraline)(sertraline hydrochloride,

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) (700 Milligram) 2) (1400 Milligra-	1) Per oral 2) Per oral	☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE		18 THERAPY DATES(From/To)	19 THERAPY DURATION
1)	2)	1) 17/JAN/2018 2) 17/JAN/2018	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER

MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO 2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER 29/MAY/2019

24d REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT 24/JUN/2021

25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	17/Jan/2018
Seq No	:	2
Reaction	:	AVSIKTLIG ÖVERDOS (Overdose intentional)
Start Date	:	17/Jan/2018
Seq No	:	3
Reaction	:	MEDVETSLÖS (Unconscious)
Start Date	:	17/Jan/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 17-årig flicka. Den medicinska historien inkluderade diab etes.
Rapporterat misstänkt läkemedel var Dasselta (desloratadine), Lergigan (promethazine), Oralin (sertraline). R apporterat som avsiktlig självdestruktiv handling,
avsiktlig överdos, medvetslös.
Ur rapport "nu på iva".
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 17/JAN/2018 - 17/JAN/2018
Seq No	:	2
Drug	:	Oralin(sertraline hydrochloride, sertraline)(sertraline hydrochloride, sertraline)
Daily Dose	:	1) (1400 Milligram)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 17/JAN/2018 - 17/JAN/2018
Seq No	:	3
Drug	:	Dasselta(desloratadine)(desloratadine)
Daily Dose	:	1) (70 Milligram)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 17/JAN/2018 - 17/JAN/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR
	SVERIGE				16	Man	14	MAY	2018

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

SUICID FÖRSÖK (Suicide attempt) - Okänd
Protocol relatedness:
As per reporter:
As per company:

TAKYKARD (Tachycardia) - Okänd
Protocol relatedness:
As per reporter:
As per company:

KRÅKTS (Vomited) - Okänd
Protocol relatedness:

Cont...

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine
2) sertraline(Sertraline)(Sertraline)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION
1) 30-40 lergigan - 2) 10 st sertralin-	1) Per oral 2) Per oral

21 DID EVENT REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 14/MAY/2018 2) 14/MAY/2018	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER	24d REPORT SOURCE
29/MAY/2019	☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER
DATE OF THIS REPORT: 24/JUN/2021	25a REPORT TYPE: ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	14/May/2018
Seq No	:	2
Reaction	:	SUICID FÖRSÖK (Suicide attempt)
Start Date	:	14/May/2018
Seq No	:	3
Reaction	:	TAKYKARD (Tachycardia)
Start Date	:	14/May/2018
Seq No	:	4
Reaction	:	KRÄKTS (Vomited)
Start Date	:	14/May/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 16-årig pojke.
Rapporterat misstänkt läkemedel var 30-40 Lergigan (promethazine) 25 mg, 10 st. fluoxetine 20 mg, 10 st sertr aline 50 mg.
Rapporterat som avsiktlig överdosering, suicid försök. Två timmar efter intag är pojken på sjukhus, har " kräkts 2 ggr-kollade ej om tabl kom upp", mår bra, "EKG ua, vitala parametrar fina, lite takykard 120-130, ga nska stressad och ledsen". Rekommenderar ev kol om enkelt att utföra.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Daily Dose	:	1) 30-40 lergigan 25 mg
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 14/MAY/2018 - 14/MAY/2018
Seq No	:	2
Drug	:	sertraline(Sertraline)(Sertraline)
Daily Dose	:	1) 10 st sertralin, 50 mg
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 14/MAY/2018 - 14/MAY/2018
Seq No	:	3
Drug	:	fluoxetine(Fluoxetine)(Fluoxetine)
Daily Dose	:	1) 10 st fluoxetin, 20 mg
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 14/MAY/2018 - 14/MAY/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	2 DATE OF BIRTH MO	2 DATE OF BIRTH YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	4-6 REACTION ONSET MO	4-6 REACTION ONSET YR
	SVERIGE				18	Kvinna	08	APR	2019

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

SUICIDSYFTE (Suicidal intention) - Okänd
Protocol relatedness:
As per reporter:
As per company:

VIDA PUPILLER (Dilatation pupillary) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

Cont...

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Propavan(propiomazine maleate, propiomazine)(propiomazine maleate,
2) melatonin(Melatonin)(Melatonin)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) (500 Milligram) 2)	1) Per oral 2) Per oral	☐ YES ☐ NO ☐ NA
17 INDICATIONS FOR USE 1)	2)	
18 THERAPY DATES(From/To) 1) 08/APR/2019 2) 08/APR/2019	19 THERAPY DURATION 1) 2)	

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER

MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO 2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER 29/MAY/2019

24d REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT 24/JUN/2021

25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	08/Apr/2019
Seq No	:	2
Reaction	:	SUICIDSYFTE (Suicidal intention)
Start Date	:	08/Apr/2019
Seq No	:	3
Reaction	:	VIDA PUPILLER (Dilatation pupillary)
Start Date	:	08/Apr/2019

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 18-årig kvinna.
Rapporterat misstänkt läkemedel var "500 mg" Propavan (propiomazine), Theralen (alimemazine), fluoxetine, lam otrigine, melatonin. Uppger 100 tabletter men enligt personal på kvinnans boende saknas ej så många.
Rapporterat som avsiktlig överdosering, suicidsyfte. Tidpunkt för intag okänt. Kvinnan hittades på sitt boe nde en timme före samtalet till Giftinformationscentralen.
Har vida pupiller, RLS 1, stabila vitalparametrar och fint EKG.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Propavan(propiomazine maleate, propiomazine)(propiomazine maleate, propiomazine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 08/APR/2019 - 08/APR/2019
Seq No	:	2
Drug	:	melatonin(Melatonin)(Melatonin)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 08/APR/2019 - 08/APR/2019
Seq No	:	3
Drug	:	fluoxetine(Fluoxetine)(Fluoxetine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 08/APR/2019 - 08/APR/2019
Seq No	:	4
Drug	:	Theralen(alimemazine, alimemazine hemitartrate)(alimemazine, alimemazine hemitartrate)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 08/APR/2019 - 08/APR/2019
Seq No	:	5
Drug	:	lamotrigine(Lamotrigine)(Lamotrigine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 08/APR/2019 - 08/APR/2019

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted] (0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				16	Kvinna	17	APR	2018	

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

SVÅRVÄCKT (Hard to awaken) - Okänd
Protocol relatedness:
As per reporter:
As per company:

TAKYKARD (Tachycardia) - Okänd
Protocol relatedness:

Cont...

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine
2) venlafaxine(Venlafaxine)(Venlafaxine)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) (2 Gram) 2) (1.5 Gram)	1) Per oral 2) Per oral	☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 16/APR/2018 2) 16/APR/2018	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted] (0)

24c DATE RECEIVED BY MANUFACTURER
29/MAY/2019

24d REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
24/JUN/2021

25a REPORT TYPE
☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	17/Apr/2018
Seq No	:	2
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	17/Apr/2018
Seq No	:	3
Reaction	:	SVÅRVÄCKT (Hard to awaken)
Start Date	:	17/Apr/2018
Seq No	:	4
Reaction	:	TAKYKARD (Tachycardia)
Start Date	:	17/Apr/2018
Seq No	:	5
Reaction	:	BLEK (Pale)
Start Date	:	17/Apr/2018
Seq No	:	6
Reaction	:	EKG FÖRÄNDRINGAR AV OKLAR NATUR, DUBBELPUCKIG T-VÅG (Electrocardiogram T wave abnormal)
Start Date	:	17/Apr/2018
Seq No	:	7
Reaction	:	MUSKELRYCKNINGAR (Muscle twitching)
Start Date	:	17/Apr/2018
Seq No	:	8
Reaction	:	LÅGT BLODTRYCK (Blood pressure low)
Start Date	:	17/Apr/2018
Seq No	:	9
Reaction	:	TRÖTT (Tiredness)
Start Date	:	17/Apr/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

BLEK (Pale) - Okänd
Protocol relatedness:
As per reporter:
As per company:

EKG FÖRÄNDRINGAR AV OKLAR NATUR, DUBBELPUCKIG T-VÅG (Electrocardiogram T wave abnormal) - Okänd
Protocol relatedness:
As per reporter:
As per company:

MUSKELRYCKNINGAR (Muscle twitching) - Okänd
Protocol relatedness:
As per reporter:
As per company:

LÅGT BLODTRYCK (Blood pressure low) - Okänd
Protocol relatedness:
As per reporter:
As per company:

TRÖTT (Tiredness) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 16-årig flicka. Den medicinska historien inkluderade ång est och åtstörningar.

Rapporterat misstänkt läkemedel var troligen ("kan vara mer") 2 g Lergigan (promethazine), 1.5 g venlafaxine depot samt "mindre mängd" melatonin. Inkommer till sjukhus 10-11 timmar efter intag av läkemedel. Rapporterat som avsiktlig självdestruktiv handling, avsiktlig överdosering. Hon är svårväckt, takykard 130-140, lågt blodtryck 100, blek, ekg förändringar av oklar natur, dubbelpuckig t-våg, ingen st-sänkning, "QTc 426". Syr esättning, venös blodgas, elektrolyter, blodstatus u.a. Temp 36,7, tappad på 780 ml urin.
Efter ytterligare ett dygn andas hon bra, är fortfarande trött samt har lite muskelryckningar, "varit takykar d nu 75 i puls".
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 16/APR/2018 - 16/APR/2018

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Seq No	:	2
Drug	:	venlafaxine(Venlafaxine)(Venlafaxine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 16/APR/2018 - 16/APR/2018

Seq No	:	3
Drug	:	melatonin(Melatonin)(Melatonin)
Daily Dose	:	1) "mindre mängd"
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 16/APR/2018 - 16/APR/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR
	SVERIGE				16	Kvinna	25	JAN	2018

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

YR (Dizzy) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG ÖVERDOS (Overdose intentional) - Okänd
Protocol relatedness:
As per reporter:
As per company:

ILLAMÅENDE (Nausea) - Okänd
Protocol relatedness:
As per reporter:
As per company:

TRÖTT (Tiredness) - Okänd
Protocol relatedness:

Cont...

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) promethazine(Promethazine)(Promethaz-
2) fluoxetine(Fluoxetine)(Fluoxetine)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) (75 Milligram) 2) (40 Milligram)	1) Per oral 2) Per oral	☐ YES ☐ NO ☐ NA
17 INDICATIONS FOR USE 1) 2)		
18 THERAPY DATES(From/To) 1) 25/JAN/2018 2) 25/JAN/2018	19 THERAPY DURATION 1) 2)	

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO 2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER 29/MAY/2019

24d REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT 24/JUN/2021

25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	YR (Dizzy)
Start Date	:	25/Jan/2018
Seq No	:	2
Reaction	:	AVSIKTLIG ÖVERDOS (Overdose intentional)
Start Date	:	25/Jan/2018
Seq No	:	3
Reaction	:	ILLAMÅENDE (Nausea)
Start Date	:	25/Jan/2018
Seq No	:	4
Reaction	:	TRÖTT (Tiredness)
Start Date	:	25/Jan/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

Case level outcome :Okänd

2019-009822 (0.0)
Rapport från Giftinformationscentralen angående en 16-årig flicka.
Rapporterat misstänkt läkemedel var fluoxetine 20 mg (2 st istället förl st) samt promethazine 25 mg (3 st istället för 1 st).

Rapporterat som yr, avsiktlig överdos, illamående, trött.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	promethazine(Promethazine)(Promethazine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 25/JAN/2018 - 25/JAN/2018
Seq No	:	2
Drug	:	fluoxetine(Fluoxetine)(Fluoxetine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 25/JAN/2018 - 25/JAN/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	2 DATE OF BIRTH MO	2 DATE OF BIRTH YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	4-6 REACTION ONSET MO	4-6 REACTION ONSET YR
	SVERIGE				19	Kvinna	21	APR	2018

7 +13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

KRÅKTS (Vomited) - Okänd
Protocol relatedness:
As per reporter:
As per company:

MEDVETANDESÄNKT RLS 2 MOT 3 (Consciousness decreased) - Okänd
Protocol relatedness:

Cont...

8 -12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Propavan(propiomazine maleate, propiomazine)(propiomazine maleate,
2) Equasym(methylphenidate hydrochloride,

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) 2)	1) Per oral 2) Per oral	☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 21/APR/2018 2) 21/APR/2018	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY
No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER	24d REPORT SOURCE
29/MAY/2019	☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER
DATE OF THIS REPORT 24/JUN/2021	25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	21/Apr/2018
Seq No	:	2
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	21/Apr/2018
Seq No	:	3
Reaction	:	KRÄKTS (Vomited)
Start Date	:	21/Apr/2018
Seq No	:	4
Reaction	:	MEDVETANDESÄNKT RLS 2 MOT 3 (Consciousness decreased)
Start Date	:	21/Apr/2018
Seq No	:	5
Reaction	:	TAKYKARD (Tachycardia)
Start Date	:	21/Apr/2018
Seq No	:	6
Reaction	:	VIDA PUPILLER (Dilatation pupillary)
Start Date	:	21/Apr/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

TAKYKARD (Tachycardia) - Okänd
Protocol relatedness:
As per reporter:
As per company:

VIDA PUPILLER (Dilatation pupillary) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 19-årig kvinna.
Rapporterat misstänkt läkemedel var Equasym (methylphenidate), Propavan (propiomazine). Intagen dos av propav
an 25 mg "minst 40 st", intagen dos av equasym 20 mg "10 st men kan vara fler".
Rapporterat som avsiktlig självdestruktiv handling, avsiktlig överdosering, kräkts, medvetandesänkt rls 2 m
ot 3, takykard, vida pupiller.
Ur rapport: kvinnan kräkts upp mycket och mycket hela tabletter, pupiller reagerar på ljus, ger ingen kontakt
, reagerar inte på smärtstillande, rycker med huvudet och kastar det fram och tillbaka.

Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Propavan(propiomazine maleate, propiomazine)(propiomazine maleate, propiomazine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 21/APR/2018 - 21/APR/2018
Seq No	:	2
Drug	:	Equasym(methylphenidate hydrochloride, methylphenidate)(methylphenidate hydrochloride, methylphenidate)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 21/APR/2018 - 21/APR/2018

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4 -6 REACTION ONSET DA	MO	YR
	SVERIGE				18	Man	10	FEB	2019

8 -12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

7 +13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

SLUDDRIG (Slurred speech) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

Cont...

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine
2) Concerta(methylphenidate hydrochloride, methylphenidate,

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE
1) (200 Milligram) 2) (216 Milligram)

16 ROUTE OF ADMINISTRATION
1) Per oral 2) Per oral

21 DID EVENT REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)
1) 10/FEB/2019 2) 10/FEB/2019

19 THERAPY DURATION
1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER
29/MAY/2019

24d REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
24/JUN/2021

25a REPORT TYPE
☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	10/Feb/2019
Seq No	:	2
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	10/Feb/2019
Seq No	:	3
Reaction	:	SLUDDRIG (Slurred speech)
Start Date	:	10/Feb/2019

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 18-årig man. Den medicinska historien inkluderade adhd. Rapporterat misstänkt läkemedel var Alvedon (paracetamol) sammanlagd dos 2000 mg, Concerta (methylphenidate) sammanlagd dos 216 mg, Ipren (ibuprofen) sammanlagd dos 2000 mg, Lergigan (promethazine) sammanlagd dos 200 mg, Medikinet (methylphenidate) sammanlagd dos 180 mg. Rapporterat som avsiktlig självdestruktiv handling, avsiktlig överdosering, sluddrig. "Mår bra, fått kol."
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 10/FEB/2019 - 10/FEB/2019
Seq No	:	2
Drug	:	Concerta(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride, methylphenidate hydrochloride, methylphenidate)(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride, methylphenidate hydrochloride, methylphenidate)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 10/FEB/2019 - 10/FEB/2019
Seq No	:	3
Drug	:	Medikinet(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride)(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride)
Daily Dose	:	1) "3 st"
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 10/FEB/2019 - 10/FEB/2019
Seq No	:	4
Drug	:	Alvedon(paracetamol)(paracetamol)
Daily Dose	:	1) (2000 Milligram)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 10/FEB/2019 - 10/FEB/2019
Seq No	:	5
Drug	:	Ipren(ibuprofen, Ibuprofen DC 85)(ibuprofen, Ibuprofen DC 85)
Daily Dose	:	1) (2000 Milligram)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 10/FEB/2019 - 10/FEB/2019

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR
	SVERIGE				18	Kvinna	05	JUL	2019

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

MEDVETANDESÅNKT (Consciousness decreased) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

Cont...

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine
2) sertraline(Sertraline)(Sertraline)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) 2)	1) Per oral 2) Per oral	☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 05/JUL/2019 2) 05/JUL/2019	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER

MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER
03/AUG/2019

24d REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
24/JUN/2021

25a REPORT TYPE
☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	05/Jul/2019
Seq No	:	2
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	05/Jul/2019
Seq No	:	3
Reaction	:	MEDVETANDESÅNKT (Consciousness decreased)
Start Date	:	05/Jul/2019

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 18-årig kvinna.
Rapporterat misstänkt läkemedel var Ipren (ibuprofen), Lergigan (promethazine), melatonin, sertraline. Intage n dos av dessa är okänd.
Rapporterat som avsiktlig självdestruktiv handling, avsiktlig överdosering, medvetandesänkt.
Kvinnan hittad "medvetandesänkt, föll till RLS 5 och nu RLS 3. Stabila parametrar".
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 05/JUL/2019 - 05/JUL/2019
Seq No	:	2
Drug	:	sertraline(Sertraline)(Sertraline)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 05/JUL/2019 - 05/JUL/2019
Seq No	:	3
Drug	:	melatonin(Melatonin)(Melatonin)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 05/JUL/2019 - 05/JUL/2019
Seq No	:	4
Drug	:	Ipren(ibuprofen, Ibuprofen DC 85)(ibuprofen, Ibuprofen DC 85)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 05/JUL/2019 - 05/JUL/2019

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				17	Kvinna	14	JUN	2018	

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING I SUICIDSYFTE (Suicidal intention) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

MÅR ILLA (Nausea) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

Cont...

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine
2) fluoxetine(Fluoxetine)(Fluoxetine)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) (750 Milligram) 2) (1200 Milligra-	1) Per oral 2) Per oral	☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 14/JUN/2018 2) 14/JUN/2018	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER	24d REPORT SOURCE
29/MAY/2019	☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER
DATE OF THIS REPORT 24/JUN/2021	25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING I SUICIDSYFTE (Suicidal intention)
Start Date	:	14/Jun/2018
Seq No	:	2
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	14/Jun/2018
Seq No	:	3
Reaction	:	MÅR ILLA (Nausea)
Start Date	:	14/Jun/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 17-årig flicka.
Rapporterat misstänkt läkemedel var Lergigan (promethazine), fluoxetine. Rapporterat som avsiktlig självdest
ruktiv handling i suicidsyfte, avsiktlig överdosering,
mår illa.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 14/JUN/2018 - 14/JUN/2018
Seq No	:	2
Drug	:	fluoxetine(Fluoxetine)(Fluoxetine)
Daily Dose	:	1) (1200 Milligram)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 14/JUN/2018 - 14/JUN/2018

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR
	SVERIGE				19	Kvinna	03	APR	2019

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

TRÖTT (Tiredness) - Okänd
Protocol relatedness:
As per reporter:
As per company:

SLÖ (Lethargy) - Okänd
Protocol relatedness:

Cont...

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine
2) Concerta(methylphenidate hydrochloride, methylphenidate,

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION
1) 25 mg a 15 st (- 2)	1) Per oral 2)

21 DID EVENT REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 03/APR/2019 2) 03/APR/2019	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER	24d REPORT SOURCE
29/MAY/2019	☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER
DATE OF THIS REPORT 24/JUN/2021	25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	03/Apr/2019
Seq No	:	2
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	03/Apr/2019
Seq No	:	3
Reaction	:	TRÖTT (Tiredness)
Start Date	:	03/Apr/2019
Seq No	:	4
Reaction	:	SLÖ (Lethargy)
Start Date	:	03/Apr/2019
Seq No	:	5
Reaction	:	MOTORISKT OROLIG (Motor restlessness)
Start Date	:	03/Apr/2019
Seq No	:	6
Reaction	:	LITE VARM (TEMP 38,1) (Slight temperature)
Start Date	:	03/Apr/2019

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

MOTORISKT OROLIG (Motor restlessness) - Okänd
Protocol relatedness:
As per reporter:
As per company:

LITE VARM (TEMP 38,1) (Slight temperature) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 19-årig kvinna.
Rapporterat misstänkt läkemedel var Concerta (methylphenidate), Lergigan (promethazine). Rapporterat som avsi
ktlig överdosering, avsiktlig självdestruktiv handling. Hon har tagit Lergigan 375 mg (25 mg a 15 st) och okl
ar mängd Concerta "em, kväll". Kvinnan är trött, slö, motoriskt orolig, lite varm (temp 38,1). "fick
lite benso".
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Daily Dose	:	1) 25 mg a 15 st (375 Milligram)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 03/APR/2019 - 03/APR/2019
Seq No	:	2
Drug	:	Concerta(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride, methylphenidate hydrochloride, methylphenidate)(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride, methylphenidate hydrochloride, methylphenidate)
Therapy Dates/Duration	:	1) 03/APR/2019 - 03/APR/2019

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4 -6 REACTION ONSET DA	MO	YR	8 -12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				19	Kvinna	29	MAY	2018	

7 +13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

URINRETENTION (Urinary retention) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

Cont...

☐ PATIENT DIED
☐ LIFE THREATENING
☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
☐ CONGENITAL ANOMALY
☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine
2) fluoxetine(Fluoxetine)(Fluoxetine)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) (500 Milligram) 2) 20 stycken fluo-	1) Per oral 2) Per oral	☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE	
1)	2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 29/MAY/2019 2) 29/MAY/2018	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER	24d REPORT SOURCE
29/MAY/2019	☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER
DATE OF THIS REPORT 24/JUN/2021	25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	29/May/2018
Seq No	:	2
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	29/May/2018
Seq No	:	3
Reaction	:	URINRETENTION (Urinary retention)
Start Date	:	30/May/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 19-årig kvinna.
Rapporterat misstänkt läkemedel var Lergigan (promethazine) och fluoxetine intag kl. 22.
Rapporterat som avsiktlig överdosering, avsiktlig självdestruktiv handling. Behandlats med kol i ambulansen.
Fyra timmar efter intag kontaktas Giftinformationscentralen , "kvinnan är sänkt av och till vaknar till inte adekvat sover där emellan". Har urinretention.
Diskuterar behandling av antikolinerga symtom, rekommenderar att börja med diazepam.
Framkommer att kvinnan "har massa piller lila och gröna i handväskan".
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 29/MAY/2019 - 29/MAY/2019
Seq No	:	2
Drug	:	fluoxetine(Fluoxetine)(Fluoxetine)
Daily Dose	:	1) 20 stycken fluoxetine 20 mg
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 29/MAY/2018 - 29/MAY/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4 -6 REACTION ONSET DA	MO	YR	8 -12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				14	Kvinna		AUG	2018	

7 +13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

KRÅKTS (Vomited) - Okänd
Protocol relatedness:
As per reporter:
As per company:

TRÖTT (Tiredness) - Okänd
Protocol relatedness:
As per reporter:
As per company:

SLÖ (Lethargy) - Okänd
Protocol relatedness:

Cont...

☐ PATIENT DIED
☐ LIFE THREATENING
☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
☐ CONGENITAL ANOMALY
☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Propavan(propiomazine maleate, propiomazine)(propiomazine maleate,
2) Ritalin(methylphenidate hydrochloride,

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE
1) "troligen" 3x25- 2) "troligen" 2 Ri-

16 ROUTE OF ADMINISTRATION
1) Per oral 2) Per oral

21 DID EVENT REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)
1) 16/AUG/2018 2) 16/AUG/2018

19 THERAPY DURATION
1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER

MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER
29/MAY/2019

24d REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
24/JUN/2021

25a REPORT TYPE
☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	16/Aug/2018
Seq No	:	2
Reaction	:	KRÄKTS (Vomited)
Start Date	:	16/Aug/2018
Seq No	:	3
Reaction	:	TRÖTT (Tiredness)
Start Date	:	/Aug/2018
Seq No	:	4
Reaction	:	SLÖ (Lethargy)
Start Date	:	/Aug/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 14-årig flicka.
Rapporterat misstänkt läkemedel var Propavan (propiomazine), Ritalin (methylphenidate). Även hasch. Intag vid kl 20.00.
Rapporterat som avsiktlig överdosering. Flickan hade kräkts fem gånger mellan kl 21.20 och 22.30, vid kl 00.20 "nu trött och slö".
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Propavan(propiomazine maleate, propiomazine)(propiomazine maleate, propiomazine)
Daily Dose	:	1) "troligen" 3x25 mg
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 16/AUG/2018 - 16/AUG/2018
Seq No	:	2
Drug	:	Ritalin(methylphenidate hydrochloride, methylphenidate)(methylphenidate hydrochloride, methylphenidate)
Daily Dose	:	1) "troligen" 2 Ritalin, oklar styrka
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 16/AUG/2018 - 16/AUG/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				17	Kvinna	22	JUN	2019	

7 +13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

RLS 2-3 (Consciousness decreased) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

Cont...

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine
2) Imovane(zopiclone)(zopiclone)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) "upp till 18 st- 2) "kanske 10 st u-	1) Per oral 2) Per oral	☐ YES ☐ NO ☐ NA
17 INDICATIONS FOR USE 1) 2)		
18 THERAPY DATES(From/To) 1) 22/JUN/2019 2) 22/JUN/2019	19 THERAPY DURATION 1) 2)	

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER

MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO 2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER 03/AUG/2019

24d REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT 24/JUN/2021

25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	22/Jun/2019
Seq No	:	2
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	22/Jun/2019
Seq No	:	3
Reaction	:	RLS 2-3 (Consciousness decreased)
Start Date	:	22/Jun/2019

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 17-årig flicka.
Rapporterat misstänkt läkemedel var Imovane (zopiclone), Lergigan (promethazine), fluoxetine, melatonin, oxazepam, intag "senast kl 13, lite närsomhelst på morgon innan det". Flickan hade även "haft tillgång" till Januvia, metformin, felodipin, metoprolol, Salures, atorvastatin, esomeprazol, Trombyl, candesartan och Atarax.
Rapporterat som avsiktlig överdosering, avsiktlig självdestruktiv handling. Vid kl 16 beskrivs flickan som RLS 2-3, "väckbar, om ropar riktigt högt". EKG visar "inget uppenbart konstigt", lugn, regelbunden frekvens "61", "andas okej, saturerar sig bra".
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Daily Dose	:	1) "upp till 18 st"x25 mg
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 22/JUN/2019 - 22/JUN/2019
Seq No	:	2
Drug	:	Imovane(zopiclone)(zopiclone)
Daily Dose	:	1) "kanske 10 st upp till 20 st"
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 22/JUN/2019 - 22/JUN/2019
Seq No	:	3
Drug	:	melatonin(Melatonin)(Melatonin)
Daily Dose	:	1) "oklart hur många, burk med 100, hälften är kvar" (3 mg)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 22/JUN/2019 - 22/JUN/2019
Seq No	:	4
Drug	:	fluoxetine(Fluoxetine)(Fluoxetine)
Daily Dose	:	1) Max 10 st x 20 mg "oklart om överdoserat"
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 22/JUN/2019 - 22/JUN/2019
Seq No	:	5
Drug	:	oxazepam(Oxazepam)(Oxazepam)
Daily Dose	:	1) "upp till 20 st", okänd styrka
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 22/JUN/2019 - 22/JUN/2019

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR
	SVERIGE				17	Kvinna	02	MAY	2018

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

7 +13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

MOTORISKT OROLIG (Restlessness) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

Cont...

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine
2) fluoxetine(Fluoxetine)(Fluoxetine)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) "upp till 48 st" 2) "upp till 50 st-	1) Per oral 2) Per oral	☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1)
2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 02/MAY/2018 2) 02/MAY/2018	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY
No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER
29/MAY/2019

24d REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
24/JUN/2021

25a REPORT TYPE
☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	02/May/2018
Seq No	:	2
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	02/May/2018
Seq No	:	3
Reaction	:	MOTORISKT OROLIG (Restlessness)
Start Date	:	02/May/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 17-årig flicka.

Rapporterat misstänkt läkemedel var Lergigan (promethazine) "upp till 48 st", 8 st Propavan (propiomazine), f luoxetine "upp till 50 st". Inkommer till sjukhus 1.5-2 timmar efter intag av läkemedel.
Rapporterat som avsiktlig överdosering, avsiktlig självdestruktiv handling. Flickan är helt klar och vaken, lite motoriskt orolig "och svårt psykiskt".
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 02/MAY/2018 - 02/MAY/2018
Seq No	:	2
Drug	:	fluoxetine(Fluoxetine)(Fluoxetine)
Daily Dose	:	1) "upp till 50 st "
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 02/MAY/2018 - 02/MAY/2018
Seq No	:	3
Drug	:	Propavan(propiomazine maleate, propiomazine)(propiomazine maleate, propiomazine)
Daily Dose	:	1) "8 st"
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 02/MAY/2018 - 02/MAY/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				17	Kvinna		MAY	2019	

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

MYOKLONIER (Myoclonus) - Okänd
Protocol relatedness:
As per reporter:
As per company:

HYPERREFLEXI (Hyperreflexia) - Okänd
Protocol relatedness:

Cont...

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine
2) sertraline(Sertraline)(Sertraline)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE
1) Anges 100 eller-
2) Anges 100 eller-

16 ROUTE OF ADMINISTRATION
1) Per oral
2) Per oral

21 DID EVENT REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1)
2)

18 THERAPY DATES(From/To)
1) 23/MAY/2019
2) 23/MAY/2019

19 THERAPY DURATION
1)
2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER
29/MAY/2019

24d REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
24/JUN/2021

25a REPORT TYPE
☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	23/May/2019
Seq No	:	2
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	23/May/2019
Seq No	:	3
Reaction	:	MYOKLONIER (Myoclonus)
Start Date	:	/May/2019
Seq No	:	4
Reaction	:	HYPERREFLEXI (Hyperreflexia)
Start Date	:	/May/2019

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 17-årig flicka med ADD och autism.
Rapporterat misstänkt läkemedel var 100 eller 200x25 mg Lergigan (promethazine), 4 st Waran (warfarin) och 10
0 eller 200 x25 eller 50 mg sertraline, "hämtat ut nyligen, tomma förpackningar nu". Rapporterat som avsiktli
g överdosering, avsiktlig självdestruktiv handling. Flickan genomgick ventrikelsköljning och fick kol. Cirka
7 timmar efter intag tillkomst av myoklonier och hyperreflexi trots sedering med Propfol, samt "ngt sträckkram
psliknande" som svarade på Stesolid. Afebril (36,6 grader), "fint EKG".
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Daily Dose	:	1) Anges 100 eller 200x25 mg, samt "hämtat ut nyligen, tomma förpackningar nu "
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 23/MAY/2019 - 23/MAY/2019
Seq No	:	2
Drug	:	sertraline(Sertraline)(Sertraline)
Daily Dose	:	1) Anges 100 eller 200x25 eller 50 mg, samt "hämtat ut nyligen, tomma förpack ningar nu"
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 23/MAY/2019 - 23/MAY/2019
Seq No	:	3
Drug	:	Waran(warfarin sodium, warfarin)(warfarin sodium, warfarin)
Daily Dose	:	1) 4 st
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 23/MAY/2019 - 23/MAY/2019

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE	3 SEX	4-6 REACTION ONSET DA	MO	YR	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				YRS 16	Kvinna		AUG	2018	

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 16-årig flicka.
Rapporterat misstänkt läkemedel var Propavan (propiomazine), fluoxetine.

Cont...

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Propavan(propiomazine maleate, propiomazine)(propiomazine maleate,
2) fluoxetine(Fluoxetine)(Fluoxetine)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) 5 st 2) (140 Milligram)	1) Per oral 2) Per oral	☐ YES ☐ NO ☐ NA
17 INDICATIONS FOR USE 1) 2)		
18 THERAPY DATES(From/To) 1) /Aug/2018 - 2) /Aug/2018 -	19 THERAPY DURATION 1) 2)	

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO 2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER 29/MAY/2019

24d REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT 24/JUN/2021

25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	/Aug/2018
Seq No	:	2
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	/Aug/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

Rapporterat som avsiktlig självdestruktiv handling, avsiktlig överdosering.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Propavan(propiomazine maleate, propiomazine)(propiomazine maleate, propiomazine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) /Aug/2018 - /AUG/2018
Seq No	:	2
Drug	:	fluoxetine(Fluoxetine)(Fluoxetine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) /Aug/2018 - /AUG/2018

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR
	SVERIGE				14	Man	13	FEB	2019

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

MÅR ILLA (Nausea) - Okänd
Protocol relatedness:
As per reporter:
As per company:

SMÅ PUPILLER (Constricted pupils) - Okänd
Protocol relatedness:

Cont...

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine
2) lamotrigine(Lamotrigine)(Lamotrigine)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE
1) (950 Milligram) 2)

16 ROUTE OF ADMINISTRATION
1) Per oral 2)

21 DID EVENT REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)
1) 13/FEB/2019 2) 13/FEB/2019

19 THERAPY DURATION
1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER
29/MAY/2019

24d REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
24/JUN/2021

25a REPORT TYPE
☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	13/Feb/2019
Seq No	:	2
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	13/Feb/2019
Seq No	:	3
Reaction	:	MÅR ILLA (Nausea)
Start Date	:	13/Feb/2019
Seq No	:	4
Reaction	:	SMÅ PUPILLER (Constricted pupils)
Start Date	:	13/Feb/2019
Seq No	:	5
Reaction	:	KÄNNER SIG LITE SKAKIG (Shaky feelings)
Start Date	:	13/Feb/2019
Seq No	:	6
Reaction	:	TRÖTT (Tiredness)
Start Date	:	13/Feb/2019

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

KÄNNER SIG LITE SKAKIG (Shaky feelings) - Okänd
Protocol relatedness:
As per reporter:
As per company:

TRÖTT (Tiredness) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 14-årig pojke, ca 55 kg.
Rapporterat misstänkt läkemedel var 38 tabletter Lergigan (promethazine) 25 mg, fluoxetine 20 mg (oklar uppgi
ft om dos 120 eller 200 mg), lamotrigine 5 mg (oklar uppgift 120 eller 200 mg). Inkommer till sjukhus ca 1
timme och 15 minuter efter intaget. Rapporterat som avsiktlig överdosering, avsiktlig självdestruktiv handlin
g, mår illa, små pupiller, känner sig lite skakig, trött men lättväckt. Vaken, pratbar, "puls" (oklart va
d som avses) samt "SR 109". Pojken vill ej dricka kol. Avvaktar med Fysiostigmin.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
Pojken har "för en kort tid sedan tagit ungefär dubbla Lergigandosen och vårdats för detta".

All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 13/FEB/2019 - 13/FEB/2019
Seq No	:	2
Drug	:	lamotrigine(Lamotrigine)(Lamotrigine)
Therapy Dates/Duration	:	1) 13/FEB/2019 - 13/FEB/2019
Seq No	:	3
Drug	:	fluoxetine(Fluoxetine)(Fluoxetine)
Therapy Dates/Duration	:	1) 13/FEB/2019 - 13/FEB/2019

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4 -6 REACTION ONSET DA	MO	YR	8 -12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	SVERIGE				16	Kvinna	12	AUG	2018	

7 +13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

TAKYKARD (Tachycardia) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

Cont...

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Propavan(propiomazine maleate, propiomazine)(propiomazine maleate,

2) Theralen(alimemazine, alimemazine hemitartrate)(alimemazine,

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION	21 DID EVENT REAPPEAR AFTER REINTRODUCTION?
1) 2)	1) Per oral 2) Per oral	☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 12/AUG/2018 2) 12/AUG/2018	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER
29/MAY/2019

24d REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
24/JUN/2021

25a REPORT TYPE
☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed BMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	12/Aug/2018
Seq No	:	2
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	12/Aug/2018
Seq No	:	3
Reaction	:	TAKYKARD (Tachycardia)
Start Date	:	12/Aug/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 16-årig flicka.
Rapporterat misstänkt läkemedel var "en veckas dos" av Concerta (methylphenidate), Propavan (propiomazine), T
heralen (alimemazine). Alkohol.
Rapporterat som avsiktlig självdestruktiv handling, avsiktlig överdosering. En timme efter intag beskrivs fli
ckan må bra men är takykard "160". "dricker kol nu"
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Propavan(propiomazine maleate, propiomazine)(propiomazine maleate, propiomazine)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 12/AUG/2018 - 12/AUG/2018
Seq No	:	2
Drug	:	Theralen(alimemazine, alimemazine hemitartrate)(alimemazine, alimemazine hemitartrate)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 12/AUG/2018 - 12/AUG/2018
Seq No	:	3
Drug	:	Concerta(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride, methylphenidate hydrochloride, methylphenidate)(methylphenidate hydrochloride, methylphenidate, methylphenidate, methylphenidate hydrochloride, methylphenidate hydrochloride, methylphenidate)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 12/AUG/2018 - 12/AUG/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR
	SVERIGE				13	Kvinna	04	MAR	2019

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

FÖRVIRRAD (Confused) - Okänd
Protocol relatedness:
As per reporter:
As per company:

HALLUCINERAR (Hallucination) - Okänd
Protocol relatedness:

Cont...

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine
2) fluoxetine(Fluoxetine)(Fluoxetine)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE
1)
2)

16 ROUTE OF ADMINISTRATION
1) Per oral
2)

21 DID EVENT REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1)
2)

18 THERAPY DATES(From/To)
1) 04/MAR/2019
2) 04/MAR/2019

19 THERAPY DURATION
1)
2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER
29/MAY/2019

24d REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
24/JUN/2021

25a REPORT TYPE
☒ INITIAL ☐ FOLLOWUP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	04/Mar/2019
Seq No	:	2
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	04/Mar/2019
Seq No	:	3
Reaction	:	FÖRVIRRAD (Confused)
Start Date	:	04/Mar/2019
Seq No	:	4
Reaction	:	HALLUCINERAR (Hallucination)
Start Date	:	04/Mar/2019
Seq No	:	5
Reaction	:	MOTORISKT OROLIG, KLIAR SIG I ANSIKTET (Motor restlessness)
Start Date	:	04/Mar/2019

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

MOTORISKT OROLIG, KLIAR SIG I ANSIKTET (Motor restlessness) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 13-årig flicka . Den medicinska historien inkluderade dep ression, ångest. Flickan inkommer 16:30 på grund av en ångestattack, "tagit 1 tabl Lergigan" flickan är "osammanhängande, plockar och griper, hallucinerar", motoriskt orolig, kliar sig i ansiktet "pappa haft tillgång till 4 tabl, hemmavid på mammas sida - zopiklon, xanor." Puls 100, syrabas ua.
Rapporterat misstänkt läkemedel var Lergigan (promethazine), fluoxetine. Rapporterat som avsiktlig överdoser ing, avsiktlig självdestruktiv handling, förvirrad, hallucinerar, motoriskt orolig, kliar sig i ansiktet.
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 04/MAR/2019 - 04/MAR/2019
Seq No	:	2
Drug	:	fluoxetine(Fluoxetine)(Fluoxetine)
Therapy Dates/Duration	:	1) 04/MAR/2019 - 04/MAR/2019

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted] (0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4 -6 REACTION ONSET DA	MO	YR
	SVERIGE				14	Kvinna		OCT	2018

8 -12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

7 +13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

MEDVETANDESÄNKT (Consciousness decreased) - Okänd
Protocol relatedness:
As per reporter:
As per company:

LÄTT TAKYKARD (Tachycardia) - Okänd
Protocol relatedness:

Cont...

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Propavan(propiomazine maleate, propiomazine)(propiomazine maleate,
2) fluoxetine(Fluoxetine)(Fluoxetine)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE
1) (3000 Milligra- 2)

16 ROUTE OF ADMINISTRATION
1) Per oral 2)

21 DID EVENT REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1) 2)

18 THERAPY DATES(From/To)
1) 28/OCT/2018 2) 28/OCT/2018

19 THERAPY DURATION
1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER
MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO
2019-[redacted] (0)

24c DATE RECEIVED BY MANUFACTURER
29/MAY/2019

24d REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☒ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
24/JUN/2021

25a REPORT TYPE
☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	28/Oct/2018
Seq No	:	2
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	28/Oct/2018
Seq No	:	3
Reaction	:	MEDVETANDESÄNKT (Consciousness decreased)
Start Date	:	/Oct/2018
Seq No	:	4
Reaction	:	LÄTT TAKYKARD (Tachycardia)
Start Date	:	/Oct/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

As per reporter:
As per company:

Case level outcome :Okänd

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 14-årig flicka.
Rapporterat misstänkt läkemedel var Propavan (propiomazine), fluoxetine. Flickan har intagit 3000 mg Propavan och eventuellt också fluoxetin "kl 17-22". Rapporterat som avsiktlig överdosering, avsiktlig självdestruktiv handling. Strax före nio morgonen efter intag beskrivs flickan som medvetandesänkt, lätt takykard, "44 qtc tid".
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Propavan(propiomazine maleate, propiomazine)(propiomazine maleate, propiomazine)
Daily Dose	:	1) (3000 Milligram)
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 28/OCT/2018 - 28/OCT/2018
Seq No	:	2
Drug	:	fluoxetine(Fluoxetine)(Fluoxetine)
Therapy Dates/Duration	:	1) 28/OCT/2018 - 28/OCT/2018

SUSPECT ADVERSE REACTION REPORT

Mfr. Control No. :2019-[redacted](0)

I REACTION INFORMATION

1 PATIENT INITIALS	1a COUNTRY	2 DATE OF BIRTH DA	MO	YR	2a AGE YRS	3 SEX	4-6 REACTION ONSET DA	MO	YR
	SVERIGE				19	Man	29	MAR	2018

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENT OR SIGNIFICANT DISABILITY/ INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

7+13 DESCRIBE REACTION(S) (include relevant test/lab data)

AVSIKTLIG ÖVERDOSERING (Intentional overdose) - Okänd
Protocol relatedness:
As per reporter:
As per company:

AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury) - Okänd
Protocol relatedness:
As per reporter:
As per company:

RLS 3 (Consciousness decreased) - Okänd
Protocol relatedness:
As per reporter:
As per company:

Case level outcome :Okänd

Cont...

II SUSPECT DRUG(S) INFORMATION

14 SUSPECT DRUG(S) (include generic name)

1) Lergigan(promethazine, promethazine
2) Imovane(zopiclone)(zopiclone)

Cont...

20 DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15 DAILY DOSE	16 ROUTE OF ADMINISTRATION
1) *kan max ha tag- 2) *kan max ha tag-	1) Per oral 2) Per oral

21 DID EVENT REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

17 INDICATIONS FOR USE
1)
2)

18 THERAPY DATES(From/To)	19 THERAPY DURATION
1) 29/MAR/2018 2) 29/MAR/2018	1) 2)

III CONCOMITANT DRUGS AND HISTORY

22 CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (Exclude those used to treat event)

Concomitant Drug Not Available

23 OTHER RELEVANT HISTORY

No Risk Factor Available

IV MANUFACTURER

24a NAME AND ADDRESS OF MANUFACTURER

MPA
Läkemedelsverket
Uppsala Science Park, Dag Hammarskjölds väg 42
Uppsala 75237 SVERIGE

24b MFR CONTROL NO 2019-[redacted](0)

24c DATE RECEIVED BY MANUFACTURER	24d REPORT SOURCE
29/MAY/2019	☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☒ HEALTH PROFESSIONAL ☐ OTHER
DATE OF THIS REPORT 24/JUN/2021	25a REPORT TYPE ☒ INITIAL ☐ FOLLOW UP ☐ FINAL

Informed EMA

Cont... = Continuation attached sheet(s)

Continuation Sheet for CIOMS report **Mfr. Control No. :2019-[redacted](0)**

Reaction Information (Cont...)

Seq No	:	1
Reaction	:	AVSIKTLIG ÖVERDOSERING (Intentional overdose)
Start Date	:	29/Mar/2018
Seq No	:	2
Reaction	:	AVSIKTLIG SJÄLVDESTRUKTIV HANDLING (Intentional self-injury)
Start Date	:	29/Mar/2018
Seq No	:	3
Reaction	:	RLS 3 (Consciousness decreased)
Start Date	:	29/Mar/2018

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

2019-[redacted] (0.0)
Rapport från Giftinformationscentralen angående en 19-årig man.
Rapporterat misstänkt läkemedel var Imovane (zopiclone), Lergigan (promethazine), Propavan (propiomazine), fluoxetine, olanzapine, omeprazole. Rapporterat
som avsiktlig överdosering, avsiktlig självdestruktiv handling. Inkom med ambulans vid kl 22, RLS 1 kl 00 och strax innan kl 02 beskrivs mannen som RLS 3. Inga avvikande "labsvar".
Förlopp: Okänd. Fallet bedömt som allvarligt, sjukhusvård.
All information finns inlagd i rapporten, ingen ytterligare information finns att efterfråga.
This report was received from the Swedish Poisons Information Centre.

Suspect Drugs (Cont...)

Seq No	:	1
Drug	:	Lergigan(promethazine, promethazine hydrochloride)(promethazine, promethazine hydrochloride)
Daily Dose	:	1) "kan max ha tagit" 12x25 mg
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 29/MAR/2018 - 29/MAR/2018
Seq No	:	2
Drug	:	Imovane(zopiclone)(zopiclone)
Daily Dose	:	1) "kan max ha tagit" 6x5 mg
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 29/MAR/2018 - 29/MAR/2018
Seq No	:	3
Drug	:	Propavan(propiomazine maleate, propiomazine)(propiomazine maleate, propiomazine)
Daily Dose	:	1) "kan max ha tagit" 6x25 mg
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 29/MAR/2018 - 29/MAR/2018
Seq No	:	4
Drug	:	olanzapine(Olanzapine)(Olanzapine)
Daily Dose	:	1) "kan max ha tagit" 6x2,5 mg
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 29/MAR/2018 - 29/MAR/2018
Seq No	:	5
Drug	:	fluoxetine(Fluoxetine)(Fluoxetine)
Daily Dose	:	1) "kan max ha tagit" 6x20 mg
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 29/MAR/2018 - 29/MAR/2018
Seq No	:	6
Drug	:	omeprazole(Omeprazole)(Omeprazole)
Daily Dose	:	1) "kan max ha tagit" 6 st
Route of Admin	:	1) Per oral
Therapy Dates/Duration	:	1) 29/MAR/2018 - 29/MAR/2018