

Instances of death in connection with Strattera treatment

Children-Adolescents:

19 suicides reported to FDA 2004-2007

(Strattera reported as *Primary Suspect Drug, PS*)

9	Years	M	6079094	LW
9	Years	M	6237403	MD
10	Years	M	5983572	MD
12	Years	M	5910416	MD
12	Years	M	6370501	CN
14	Years	M	5913951	MD
14	Years	M	6183286	CN
14	Years	M	6315638	MD
15	Years	M	5671703	MD
15	Years	M	5952177	MD
16	Years	M	5951902	OT
16	Years		6322828	CN
16	Years	M	6393534	MD
17	Years	M	4152711	MD
17	Years	M	5738728	MD
17	Years	M	5924684	
18	Years	M	4168987	MD
18	Years	M	6026869	CN
19	Years	F	5923694	MD

+12 instances of death not from suicide, FDA 2004-2007,

(Strattera reported as *Primary Suspect Drug*)

3	Years	F	6355915	MD	
5	Years	M	5882337	MD	
5	Years	M	4112478	MD	
6	Years	M	5876785	MD	
8	Years	M	4199197	MD	
9	Years	M	6164639	CN	
10	Years	M	6109466	MD	
11	Years	M	5754653	MD	
12	Years	M	4041277	MD	
12	Years		6447235	MD	
14	Years	M	6411933	MD	2007
16	Years	M	3970831	MD	

+3 additional cardiac deaths [2 of 5 fatal cardiac disorders included above] in Risk-Benefit Assessment Report from MHRA (p. 35) “During the period 26 November 2002 –

30 September 2005 there were a total of 11 case reports of cardiac disorders with a fatal outcome. **These fatal cases involved 5 children and adolescents** and 6 adults.”

+3 additional small children (under 6 mentioned in Periodic Safety

Update Report 9, PSUR 9) from Lilly (cumulative) There were 72 adverse events that were considered as serious and included in 48 serious case reports, **4 of which resulted in a fatal outcome. One fatal case was a hearsay case with no detailed information, involving a 3-year-old female who died of an unknown cause [same as case 6344915]. The second case involved a patient who died of drowning. The third case involved a 2-year-old who was taking both atomoxetine and olanzapine at high doses at the time of her death. The fourth concerned a 5-year-old male who died during a school activity, possibly due to an asthma attack.** Though the HCP reporters in the last 2 fatal cases commented that the events were unlikely associated to atomoxetine, based on the information provided, the role of atomoxetine in these 2 cases could be neither confirmed nor ruled out.

Summary children and adolescents: 19+18= 37 reported dead in FDA 2004-2007 (with Strattera as *Primary Suspect Drug*) and in PSURs (at least 23 of these reports by Health Care Professionals, HCPs.)

Adults:

+17 suicides reported to FDA 2004-2007 (Strattera reported as *Primary Suspect Drug*)

20	Years	F	5796217	OT
21	Years	M	6054812	PH
21	Years	M	6157560	
25	Years	M	6440228	MD
27	Years	M	5899462	MD
28	Years	M	6183275	CN
33	Years	F	6373005	
35	Years	F	4101722	MD
35	Years	M	4141401	MD
39	Years	M	5744981	MD
		M	5897087	
		M	5919125	
		M	5939430	
		M	6168850	MD
		M	6371858	MD
32	Years	F	5651144	MD
47	Years	M	5655897	MD

(The last two cases confirmed as fatal suicide cases in Lilly’s reports to the MHRA.)

+16 instances of death, not from suicide, FDA 2004-2007 (Strattera reported as *Primary Suspect Drug*)

20	Years	M	6164621	CN
26	Years	M	5731386	MD
27	Years	F	5996604	MD
41	Years	M	4157588	MD
42	Years	M	6353706	MD
45	Years	F	4148360	MD
46	Years	M	6046261	MD

49	Years	M	6018744	MD
50	Years	F	6234939	MD
51	Years	M	6018744	MD
65	Years	F	5862506	MD
71	Years	M	5769652	MD
		F	6043198	MD
		M	6014238	MD
		F	6508341	CN
		F	5764249	MD

+4 additional cardiac deaths in Risk-Benefit Assessment Report from

MHRA (p. 35) [2 of the 6 already counted above]“During the period 26 November 2002 – 30 September 2005 there were a total of 11 case reports of cardiac disorders with a fatal outcome. These fatal cases involved 5 children and adolescents and **6 adults.**”

+ 7 stillbirth/abortion spontaneous FDA 2004-2007

(Strattera reported as *Primary Suspect Drug*)

	Stillbirth		6041125	MD
	Stillbirth		6045434	
	Abortion Spontaneous	F	4205958	
22	Abortion Spontaneous	F	5752581	OT
25	Abortion Spontaneous	F	6384021	CN
38	Abortion Spontaneous	F	5752476	CN
	Abortion Induced		4148345	MD

Summary adults, stillbirth/abortion spontaneous:

17+20+7= 44 reported dead in FDA 2004-2007 (with Strattera as *Primary Suspect Drug*) **and in PSURs** (at least 24 of these reports by HCPs.)

SUMMARY FROM FDA 2004-2007 AND PSURs:

37 children and adolescents + 37 adults + 7 stillbirth/abortion spontaneous = 81 deaths

(At least 47 of these reports by HCPs.)

In addition the following fatal cases in connection with Strattera treatment – with Strattera as Secondary Suspect Drug (SS) or with concomitant drugs (C) – are reported to FDA 2004-2007:

Children-Adolescents:

3 additional suicides

9	Years	M	6237403	MD
18	Years	F	6169250	OT
18	Years	F	6191766	OT

1 additional death

12	Years	F	5778437	MD
----	-------	---	---------	----

Adults:

5 additional suicides

20	Years	M	6096346	CN
21	Years	F	6385870	CN
26	Years	M	4210354	CN
50	Years	F	4220166	MD
59	Years	M	4112662	LW

5 additional deaths

38	Years	F	6229654	OT
44	Years	M	6296730	OT
46	Years	M	6106576	MD
48	Years	M	6169382	
50	Years	F	6238431	CN

SUMMARY FROM FDA 2004-2007 AND PSURs including Strattera in all Role Codes (PS, SS, C):

22 (suicides) + 19 = 41 children and adolescents;

22 (suicides) + 25 = 47 adults

+ 7 stillbirth/abortion spontaneous

= 95 reported cases of death