

Instances of death in connection with Strattera treatment

Children-Adolescents:

20 suicides reported to FDA 2004-2008 (September)
(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
14	Years	M	6617515	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

+18 instances of death not from suicide, FDA 2004-2008
(Strattera reported as *Primary Suspect Drug*)

3	Years	F	6355915	MD
5	Years	M	5882337	MD
5	Years	M	4112478	MD
5	Years	M	6102860	MD
6	Years	M	5876785	MD
7	Years	M	5890841	MD
8	Years	M	4199197	MD
10	Years	M	6109466	MD
11	Years	F	6014130	
11	Years	M	5754653	MD
12	Years		6042142	MD
12	Years	M	4041277	MD
12	Years		6447235	MD
12	Years	M	6019492	MD
13	Years	M	6694620	MD

14	Years	M	6411933	MD
14	Years		5923700	MD
16	Years	M	3970831	MD

Summary children and adolescents: 20+18= 38 reported dead in FDA 2004-2008 (with Strattera as *Primary Suspect Drug*, 30 of these reports by Health Care Professionals, HCPs).

Adults:

+20 suicides reported to FDA 2004-2008 (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
35	Years	F	6571904	CN
39	Years	M	5744981	MD
		M	5897087	
		M	5919125	
		M	5939430	
		M	6168850	MD
		M	6371858	MD
		M	6579175	MD
		M	6731814	CN
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)

+22 instances of death, not from suicide, FDA 2004-2008 (Strattera reported as *Primary Suspect Drug*)

20	Years	M	6164621	CN
26	Years	M	5731386	MD
27	Years	F	5996604	MD
33	Years	M	6076514	MD
41	Years	M	4157588	MD
42	Years	M	6353706	MD
42	Years	M	5658262	MD
45	Years	F	4148360	MD
46	Years	M	6046261	MD
47	Years	F	5655897	MD

49	Years	M	6179782	MD
50	Years	F	6234939	MD
65	Years	F	5862506	MD
71	Years	M	5769652	MD
76	Years	M	6353706	MD
		F	6043198	MD
		M	6014238	MD
		F	6508341	CN
		F	5764249	MD
		M	6551202	MD
		F	6610971	MD
		M	6642208	MD

+ 7 stillbirth/abortion spontaneous FDA 2004-2008
(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:
20+22+7= 49 reported dead in FDA 2004-2008 (with Strattera as *Primary Suspect Drug*) (at least 32 of these reports by HCPs.)

SUMMARY OF FDA 2004-2008 – Strattera as PS:
38 children and adolescents + 42 adults + 7
stillbirth/abortion spontaneous = 87 deaths
(At least 62 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 2004-2008:

Children-Adolescents:

4 additional suicides

18	Years	F	6169250	OT
18	Years	F	6191766	OT
19	Years	M	6524629	OT
19	Years	M	6558554	OT

3 additional deaths

12	Years	F	5778437	MD
14	Years		5891395	PH
17	Years	M	5737094	CN

Adults:

8 additional suicides

20	Years	M	6096346	CN
21	Years	F	6385870	CN
26	Years	M	4210354	CN
41	Years	F	5738584	MD
50	Years	F	4220166	MD
59	Years	M	4112662	LW
		M	5701390	CN
		M	6516259	OT

7 additional deaths

38	Years	F	6229654	OT
44	Years	M	6296730	OT
45	Years	F	4201758	MD
46	Years	M	6106576	MD
48	Years	M	6169382	
50	Years	F	6238431	CN
		F	5905025	MD

+ 1 stillbirth/abortion spontaneous FDA 2004-2008

Abortion Spontaneous		5788809	OT

SUMMARY FROM FDA 2004-2008 including Strattera in all Role Codes (PS, SS, C):

24 (suicides) + 21 = 45 children and adolescents;

28 (suicides) + 29 = 57 adults

+ 8 stillbirth/abortion spontaneous

= 110 reported cases of death to FDA

Added to this from Periodic Safety Update Reports (PSURs) and Risk/Benefit Report from 2006.

(The cases below are *clearly* not part of the reports submitted to FDA There are most likely also other fatal cases described by Lilly in different PSURs to MHRA, which are not part of the FDA data. These cases are not included here.)

2 years (F) “The third case involved a 2-year-old who was taking both atomoxetine and olanzapine at high doses at the time of her death.” **(sic!)** PSUR 9

13 years (M) suicide PSUR 9

16 years (M) “liver congestion consistent with dilated cardiomyopathy” Risk/Benefit Assessment Report January 2006

45 years (M) “cardiomegaly” Risk/Benefit Assessment Report January 2006

67 years (F) sudden death PSUR 9

**In total 48 children and adolescents,
59 adults, 8 stillbirth/abortion spontaneous
= 115 reported cases of death**