

Questions and Answers

Suicidal thoughts in children and adolescents treated with Strattera (atomoxetine)

1. What is Strattera (atomoxetine)?

Strattera (atomoxetine) is used to help control the symptoms of attention deficit hyperactivity disorder (ADHD - inability to pay attention and impulsiveness and hyperactivity) in children and adolescents.

Strattera is authorised for the treatment of ADHD in children of 6 years and older and in adolescents as part of a comprehensive treatment programme. Treatment must be initiated by or under the supervision of a physician with appropriate knowledge and experience in treating ADHD.

2. How long has Strattera been on the market?

Strattera has been marketed in the UK since July 2004 but has been available in the United States since November 2002.

3. How many patients are taking Strattera in the UK?

It is estimated that up to 15,000 patients have been treated with Strattera since it was marketed.

4. What is the issue?

An analysis of 12 clinical trials carried out in 1,357 children/adolescents that compared the effects of Strattera and placebo (sugar pills) in the treatment of ADHD has identified an increase in the rate of suicidal thoughts/behaviour in Strattera treated individuals compared with those receiving placebo.

There were six events occurred in those treated with Strattera - one case of suicide attempt and five of suicidal thoughts. No events occurred in 851 patients receiving placebo. The age range of children experiencing these events was seven to 12 years. It should be noted however that the number of adolescent patients included in the clinical trials was low. There were no completed suicides in these trials.

5. What advice is being given?

The Chairman of the Committee on Safety of Medicines (CSM) is writing to health professionals to advise that:

- Patients on Strattera should be monitored for signs of depression, suicidal thoughts or suicidal behaviour and referred for appropriate treatment if necessary.
- Patients and parents should be informed about this risk and advised to watch for any clinical worsening, irritability or agitation, suicidal thoughts or behaviour or other unusual changes in behaviour.

Children taking Strattera who are feeling well need not be concerned. Those who are concerned or unwell should consult their doctor to discuss the best course of action.

6. Are there alternatives to taking Strattera?

Methylphenidate (trade names are Ritalin, Concerta XL and Equasym) is an amphetamine like drug which has been available in the UK for decades and was licensed as part of a comprehensive treatment programme for attention deficit hyperactivity disorders (ADHD) in children aged 6 years and older in 1988. Treatment should be under the supervision of a specialist in childhood behavioural disorders.

7. Do these alternative treatments carry the same risk?

It is recognised that methylphenidate (trade names are Ritalin, Concerta XL and Equasym), another medicine licensed for the treatment of ADHD, may worsen an individual's underlying depression.