

10 May 2006

Questions and Answers Seroxat (Paroxetine)

◆ **What is Seroxat (paroxetine)?**

Seroxat belongs to a group of anti-depressant drugs known as selective serotonin reuptake inhibitors (SSRIs) which are effective treatments for depression and anxiety disorders. As with all antidepressants, it is recommended that Seroxat should only be used when strictly indicated and when the anticipated benefit of treating the illness is considered to outweigh any potential risk. Seroxat has been used to treat depressive illness in millions of people worldwide.

◆ **How many adults are taking Seroxat in the UK?**

It is estimated that just over 300,000 adults in the UK were prescribed Seroxat in 2005.

◆ **What is the issue?**

The MHRA has been made aware of a new analysis of Seroxat clinical trials which suggest that adults, particularly young adults with depressive illness, may be at increased risk of suicidal behaviour when treated with Seroxat.

◆ **How did this issue come about?**

GSK carried out an updated analysis of their clinical trial database in the context of an ongoing review of the risk of suicidal behaviour with SSRIs by the USA Food and Drug Administration.

◆ **What is being done to warn people of the risk of suicidal thoughts and behaviour?**

We issued advice to health professionals and patients in December 2004 on the risk of suicidal behaviour with Seroxat. This was based on the findings of an Expert Working Group of the Committee on Safety of Medicines which found an increased risk of suicidal behaviour in children taking Seroxat (and other SSRIs) and concluded that a similar increased risk of suicidal behaviour in adults could not be excluded. We are carefully reviewing the new analysis and in the mean time have written to all health professionals to remind them of the current advice that patients taking Seroxat, particularly young adults, should be carefully monitored during treatment for any worsening of symptoms or suicidal behaviour.

◆ **What is being done to investigate the safety of this drug?**

The safety of Seroxat is continually monitored by the MHRA and advice is issued as new data come to light.

◆ **What should I do if I am taking Seroxat?**

If you are taking Seroxat and are doing well on treatment there is no need to be concerned by these new data. Detailed information on your treatment is provided in the patient information leaflet which accompanies the medicine (<http://www.medicines.org.uk/searchresult.aspx?search=seroxat>).