

QUESTIONS AND ANSWERS

NEW ADVICE ON SEROXAT FROM THE COMMITTEE ON SAFETY OF MEDICINES

Q1. What is the new advice?

New advice from the government's independent scientific advisory committee, the Committee on Safety of Medicines (CSM) is that Seroxat should not be used in children and adolescents under the age of 18 for the treatment of depressive illness. This new advice follows the receipt of new data in children under 18 which shows no benefit in the treatment of depressive illness and suggests an increase in the rate of reporting of suicidal thoughts and behaviour in this age group when treated with Seroxat.

Q2. Should children on Seroxat stop taking it immediately?

It is very important that children and adolescents should not stop taking Seroxat suddenly as there is a risk of withdrawal symptoms. Children and adolescents currently taking Seroxat should consult their doctor to discuss the best course of action. If they are well on Seroxat, their doctor may advise that they complete their course of treatment. If their doctor advises that Seroxat should be stopped, this should be done gradually to minimise the risk of withdrawal symptoms.

Q3. My child is taking Seroxat for depressive illness – what should I do?

If your child is under the age of 18 and being treated with Seroxat for depressive illness you should consult their doctor for advice. Their doctor may advise completion of the planned course of treatment on Seroxat. If they are not well on Seroxat, a change of treatment should be considered.

Seroxat should not be stopped suddenly because of the risk of withdrawal reactions. Your child's doctor will advise that the dose be reduced very gradually, eventually alternating days if necessary. If the dose is not reduced gradually there is more chance of experiencing side effects. If severe unwanted side-effects occur it may be necessary to start taking Seroxat again or increase the dose before subsequently decreasing the dose more gradually.

Q4. What data is this advice based on?

Three clinical trials carried out in children (under 18 years) with depressive illness compared the effect of paroxetine and placebo (sugar pills) and found that paroxetine did not work any better than placebo in the treatment of depression. They also found a cluster of events including suicidal thoughts and behaviour. Various analyses suggest that the risk of these events is between 1.5 and 3.2 times greater with Seroxat compared to placebo. There were no deaths in these trials.

Q5. Is Seroxat licensed for the treatment of children and adolescents?

Seroxat has never been licensed for use in children and adolescents, however it is used in this age group outside its licence. Doctors may prescribe a medicine off licence if this is considered to be in the best interests of the patient.

Q6. My child is taking Seroxat for a condition other than depression – what should I do?

Seroxat has never been approved for use in children under the age of 18, however your child may have been prescribed Seroxat outside of its licence if their doctor considers it is the best treatment for their condition. If your child has been prescribed Seroxat for a reason other than depressive illness – e.g. obsessive compulsive disorder or an anxiety disorder, and you are concerned about their treatment, you should contact your doctor and discuss your concerns.

Q7. What does this mean for the use of Seroxat in adults?

CSM formally reviewed the issue of suicidal behaviour with SSRIs most recently in December 2001 and concluded that the evidence was not sufficient to confirm a causal association between SSRIs and suicidal behaviour, although an effect in a small high-risk population could not be ruled out. CSM has advised that Seroxat is an effective treatment for depressive illness and anxiety disorders and that the benefits of treatment outweigh the risks.

Q8. What advice are you giving to adults using Seroxat?

It is vital that patients are not panicked into stopping their medication suddenly. Advice to adults using Seroxat has not changed. Seroxat has been demonstrated to be effective in the treatment of depressive illness in adults (in contrast to children). The Expert Working Group of the CSM will examine urgently what implications, if any, these data have for the use of Seroxat in adults but currently, evidence suggests that the balance of risks and benefits in adults is favourable.

Anyone taking Seroxat who is feeling unwell or is concerned about their treatment, should consult their doctor.

Q9. Why would Seroxat cause these reactions in children and not in adults?

Childhood depression is different from adult depression, partly because the brain is still developing, partly because children think differently to adults and partly because children report their experiences in a different way to adults. It has only been since the 1970 and early 1980's that depression in childhood and adolescence has been recognised. A number of antidepressants that have been shown to be beneficial in adult depression have been shown not to work in childhood depression.

Children react very differently to some medicines and some side effects over a range of drugs are seen in children which are not seen in adults.

Q10. What other treatments for depression are there for children?

Child psychiatrists tend to use behavioural therapies as first line treatment for depression in children. If drug treatment is considered, there are no licensed drugs for children for the treatment of depression but your doctor may prescribe outside the licensed conditions if s/he considers that this is necessary. Fluoxetine (Prozac) has recently been licensed in the U.S for children aged 7-17 years for the treatment of depression and obsessive compulsive disorder.

Q11. What about other SSRIs?

SSRIs have been demonstrated to be effective in treating adults with depressive illness and anxiety disorders. The Expert Working Group of the CSM will examine urgently what implications, if any, these data have for the use of SSRIs in adults but currently, evidence suggests that the balance of risks and benefits in adults is favourable.

Q12. What are the implications for other antidepressant drugs?

Children

No antidepressant is currently licensed in the UK for treatment of depressive illness in children and adolescents. However major depression in children is a very serious disease and some patients require drug treatment. In this situation, doctors must use their knowledge and expertise to decide on the best course of treatment for individual patients.

Adults

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The other main class of medicines used in treatment of depression are the tricyclic antidepressants (TCAs). In terms of effectiveness, SSRIs and TCAs are very similar. However, in terms of side effects they differ. The SSRIs are not associated with side-effects of the anticholinergic type (for example constipation, urinary retention, blurred vision and dry mouth). Therefore they are more acceptable to some patients. SSRIs do not have the potential for cardiotoxicity associated with the TCAs, and they are safer if taken in overdose and can be used by patients with cardiovascular disease. Other antidepressants that are not within these two classes are available. If anyone is concerned about their treatment they should consult their doctor.

Q13. What are the adverse reactions to Seroxat?

The most common side effects recognised to occur in while on treatment with Seroxat are nausea, sweating, tremor, insomnia, diarrhoea and vomiting. Withdrawal symptoms commonly occur when Seroxat is stopped or the dose reduced. These are more likely to occur if the Seroxat is stopped suddenly which is why patients are

advised to reduce the dose gradually on stopping. Symptoms that occur on stopping or dose reduction include nausea, dizziness, headache, anxiety and electric shock sensations.

Q14. How many children are taking Seroxat in the UK?

It is estimated that there are around 4 million prescriptions for Seroxat issued in the UK every year. Of these less than 1% are estimated to be issued for children under the age of 18. We calculate that approximately 7-8,000 patients under 18 have been treated with paroxetine in the past year.

Q15. What is Seroxat?

Seroxat (paroxetine) is one of a class of medicines called the Selective Serotonin Reuptake Inhibitors (SSRIs). Others in this class are fluoxetine (Prozac), sertraline (Lustral), fluvoxamine (Faverin), citalopram (Cipramil) and escitalopram (Cipralext). SSRIs are used in the treatment of depressive illness and anxiety disorders.

Q17. How long has Seroxat been on the market?

Seroxat was first licensed in the UK in 1990 for the treatment of depressive illness. Approximately 4 million prescriptions were issued in UK last year and it is estimated that almost 17 million people worldwide have received Seroxat.

Q18. How common is suicide in children ?

Completed suicide is almost unheard of below the age of 10 and very rare between the ages of 10-14. In 15-19 year olds the rates of suicide in England and Wales in 1998 were 52 per million in males and 13 per million in females. These figures may be an underestimate because they exclude deaths of uncertain cause, some of which may have been suicides. In older children, self-harm and suicidal thoughts are much more common than completed suicide.