

SEROXAT (PAROXETINE) - *Questions and Answers*

What is Seroxat?

Seroxat is the tradename for the medicine paroxetine, which has been used successfully to treat depressive illness in millions of people worldwide.

It is a member of a group of medicines known as Selective Serotonin Reuptake Inhibitors (SSRIs). These drugs work by increasing the level of the chemical, serotonin in the brain, which helps to alleviate the symptoms of depression. Seroxat has also been shown to help patients who suffer with Anxiety, Post-Traumatic Stress Disorder, Social Anxiety, Panic disorder and Obsessive Compulsive disorder.

When Seroxat was first licensed in 1990, based on all the available data, the Committee on safety of Medicines (CSM) considered that the health benefits outweighed the risk of adverse effects.

Is it safe to carry on taking this medicine?

There has been a lot of concern raised in the media about the safety of Seroxat and we are looking carefully into these concerns, however it is important that patients who are benefiting from taking Seroxat should not be frightened into stopping their medicine. The benefits of taking Seroxat are well established. No medicine is without side effects and the side effects of Seroxat are well known and are listed in the Patient Information Leaflet that is provided each time a medicine is dispensed. If you are experiencing any side effects or have concerns about your treatment you should discuss these with your doctor.

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

The Medicines and Healthcare products Regulatory Agency and the CSM has kept the safety of Seroxat under close continuous review. The CSM has reviewed the current available data on a number of occasions particularly the data in relation to the two main areas of concern: withdrawal reactions and suicidal behaviour.

Because of continuing concerns in relation to withdrawal reactions and also suicidal behaviour, the Committee on Safety of Medicines is convening an expert subgroup to further review the safety of SSRIs and to ensure that the advice in the product information for patients and prescribers is optimal for safe use of these products.

What about patients' views – will these be taken into account during this review?

We value patients' views and believe it is vitally important that patients are given the opportunity to input into the review of the safety of SSRIs. The new CSM Expert Group will include patient representatives and information provided by patients about their experiences will be carefully reviewed.

A key output of the review is likely to be revised information for patients and we will ensure that the new information is user tested by patients.

Has the MHRA/CSM asked MIND and the Seroxat User Group for data.

We have asked MIND and the Seroxat Users group for the data that they have been collating and will ensure that this is fully assessed during the review.

Does Seroxat cause addiction?

No, this issue has been carefully reviewed and although it has always been known that Seroxat can cause withdrawal reactions when the treatment is stopped, it does not cause addiction. In the majority of patients withdrawal reactions are not serious. However it is possible that some patients may experience severe reactions. When stopping treatment with Seroxat it is important that this is done slowly and that the dose is decreased bit by bit. If you wish to stop your treatment because you feel better you should to discuss with your doctor.

What has the Government done about these worries about addiction?

The Committee on Safety of Medicines (CSM) reviewed the issue of withdrawal reactions and possible dependence with Seroxat and the other SSRIs in 1998/99 and this has also been considered in Europe by the Committee on Proprietary Medicinal Products (CPMP). The CPMP reached similar conclusions to the CSM, that although withdrawal reactions do occur with SSRIs these medicines do not cause dependence. The US Food and Drugs Administration share this view.

Can Seroxat and the other SSRIs cause suicide?

Being depressed can sometimes mean that you think about suicide and some people will try to commit suicide. It is also known that suicidal behaviour can sometimes increase in the early stages of treatment with any antidepressant and it is not until two or three weeks after starting the treatment that you will start to notice any difference and to feel better. It has been postulated that SSRIs might lead to an increased risk of suicide in a small proportion of individuals, however the CSM has reviewed this issue on numerous occasions and concluded that there was insufficient evidence to confirm an association. However the patient information leaflets with all SSRIs state that there may be an increased risk of suicide in the early stages of treatment with any antidepressant and anyone who has suicidal thoughts should seek urgent medical attention.

What has the Government done about these worries about suicide?

The Committee on Safety of Medicines has carefully considered this issue on a number of occasions over the years and have advised each time that the current evidence does not confirm an association between SSRIs and suicidal behaviour.

Shouldn't Seroxat be withdrawn from the UK market?

Seroxat is an effective treatment for depression and anxiety disorders. These serious conditions can cause severe suffering and are associated with an increased risk of suicide. Therefore, the availability of effective treatments is critically important.

The benefits of Seroxat are still considered to outweigh the risk of adverse drug reactions. The safety of Seroxat has been carefully on a number of occasions in the past. A CSM expert subgroup is being convened to consider again all the available data and what if any implications this may have for the balance of risks and benefits of paroxetine.

Should new patients be started on Seroxat?

Depression is a serious condition and can be potentially life-threatening. Seroxat has been shown to effectively reduce the symptoms of depression and anxiety disorders. The health benefits of Seroxat in the helping people with depression outweigh the risk of adverse effects and there is no reason that new patients shouldn't be started on Seroxat.

What is the yellow card scheme?

The Yellow Card Scheme for spontaneous reporting of suspected adverse drug reactions (ADRs) was introduced in 1964 after the thalidomide tragedy highlighted the urgent need for routine post-marketing surveillance of medicines. Since then more than 400,000 reports of suspected ADRs have been submitted to the CSM/MCA on a voluntary basis by doctors, dentists, pharmacists and coroners and by pharmaceutical companies under statutory obligations.