

Seroxat® 10 mg, 20 mg and 30 mg film-coated tablets

 GlaxoSmithKline

Paroxetine

Patient Information Leaflet

Eight important things you need to know about Seroxat

Please read all of the leaflet. It includes a lot of additional important information about this medicine.

- **Seroxat treats depression and anxiety disorders.** Like all medicines it can have unwanted effects. It is therefore important that you and your doctor weigh up the benefits of treatment against the possible unwanted effects, before starting treatment.
- **Seroxat is not for use in children and adolescents under 18.** See section 6, *Children and adolescents under 18*, inside this leaflet.
- **Seroxat won't work straight away.** Some people taking antidepressants feel worse before feeling better. Your doctor should ask to see you again a couple of weeks after you first start treatment. Tell your doctor if you haven't started feeling better. See section 3, *How to take your tablets*, inside this leaflet.
- **Some people who are depressed or anxious think of harming or killing themselves.** If you start to feel worse, or think of harming or killing yourself, **see your doctor or go to a hospital straight away.** See *Thoughts of harming yourself*, inside this leaflet.
- **Don't stop taking Seroxat without talking to your doctor.** If you stop taking Seroxat suddenly or miss a dose, you may get withdrawal effects. See section 5, *Stopping Seroxat*, inside this leaflet.
- **If you feel restless and feel like you can't sit or stand still, tell your doctor.** Increasing the dose of Seroxat may make these feelings worse. See section 4, *Possible side effects*, inside this leaflet.
- **Taking some other medicines with Seroxat can cause problems.** You may need to talk to your doctor. See *Other medicines and Seroxat*, inside this leaflet.
- **If you are pregnant or planning to get pregnant,** talk to your doctor. See *Pregnancy, breast-feeding and Seroxat*, inside this leaflet.

Read this leaflet. It includes a lot of important information about this medicine.

Keep this leaflet. You may need to read it again.

If you have more questions, ask your doctor or pharmacist (chemist). You may also find it helpful to contact a self-help group, or patient organisation, to find out more about your condition. Your doctor will be able to give you details.

1. What Seroxat is and what it is used for

Seroxat tablets come in three strengths. **10 mg tablets** are oval, white to pinkish white tablets and marked with "FC1" and break line on one side and "GS" and break line on the other side. **20 mg tablets** are white ovals marked "Seroxat 20" on one side. **30 mg tablets** are blue ovals marked "Seroxat 30" on one side. Each pack of Seroxat 10 mg tablets contains 4 strips of 7 tablets (28 tablets in total). Each pack of Seroxat 20 mg and 30 mg tablets contains three strips of 10 tablets (30 tablets in total).

Seroxat is a treatment for adults with depression and/or anxiety disorders.

Seroxat is one of a group of medicines called SSRIs (*selective serotonin reuptake inhibitors*). Everyone has a substance called serotonin in their brain. People who are depressed or anxious have lower levels of serotonin than others. It is not fully understood how Seroxat and other SSRIs work but they may help by increasing the level of serotonin in the brain.

Other medicines or psychotherapy can also treat depression and anxiety. Treating depression or anxiety disorders properly is important to help you get better. If it's not treated, your condition may not go away and may become more serious and more difficult to treat.

You may find it helpful to tell a friend or relative that you are depressed or suffering from an anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

2. Before you take Seroxat

Do not take Seroxat ...

- **If you are taking medicines called monoamine oxidase inhibitors (MAOIs,** including *moclobemide*), or have taken them at any time within the last two weeks. Your doctor will advise you how you should begin taking Seroxat once you have stopped taking the MAOI
- **If you are taking a tranquilliser called thioridazine**
- **If you are taking an anti-psychotic called pimozide**
- **If you have previously had an allergic reaction** to paroxetine or any of the other tablet ingredients. See section 8, *What Seroxat contains*, inside this leaflet

► **If any of these apply to you,** tell your doctor without taking Seroxat

Check with your doctor...

• Are you taking any other medicines (see *Other medicines and Seroxat*, inside this leaflet)?

- Do you have eye, kidney, liver or heart trouble?
- Do you have epilepsy or have a history of fits?
- Do you have episodes of mania (overactive behaviour or thoughts)?
- Are you having electro-convulsive therapy (ECT)?
- Do you have a history of bleeding disorders?
- Are you taking tamoxifen to treat breast cancer or fertility problems? Seroxat may make tamoxifen less effective so your doctor may recommend you take another antidepressant.
- Do you have diabetes?
- Are you on a low sodium diet?
- Do you have glaucoma (pressure in the eye)?
- Are you pregnant or planning to get pregnant (see *Pregnancy, breast-feeding and Seroxat*, inside this leaflet)?

► **If you answer YES to any of these questions,** and you have not already discussed them with your doctor, **go back to your doctor and ask what to do about taking Seroxat.**

Thoughts of suicide and worsening of your depression or anxiety disorder

If you are depressed and/or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer.

You may be more likely to think like this:

- If you have previously had thoughts about killing or harming yourself.
- If you are a **young adult.** Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

► If you have thoughts of harming or killing yourself at any time, **contact your doctor or go to a hospital straight away.**

You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

Pregnancy, breast-feeding and Seroxat

Talk to your doctor as soon as possible if you're pregnant, if you might be pregnant, or if you're planning to become pregnant. In babies whose mothers took Seroxat during the first few months of pregnancy, there have been some reports showing an increased risk of birth defects, in particular those affecting the heart. In the general population, about 1 in 100 babies are born with a heart defect. This increased to about 2 in 100 babies in mothers who took Seroxat. You and your doctor may decide that it is better for you to gradually stop taking Seroxat while you are pregnant. However, depending on your circumstances, your doctor may suggest that it is better for you to keep taking Seroxat.

If you are taking Seroxat in the last 3 months of pregnancy, let your midwife know as your baby might have some symptoms when it is born. These symptoms usually begin during the first 24 hours after the baby is born. They include not being able to

sleep or feed properly, trouble with breathing, a blue-ish skin or being too hot or cold, being sick, crying a lot, stiff or floppy muscles, lethargy, tremors, jitters or fits. If your baby has any of these symptoms when it is born and you are concerned, **contact your doctor or midwife who will be able to advise you.**

Seroxat may get into breast milk in very small amounts. If you are taking Seroxat, go back and talk to your doctor before you start breast-feeding. You and your doctor may decide that you can breast-feed while you are taking Seroxat.

Other medicines and Seroxat

Some medicines can affect the way Seroxat works, or make it more likely that you'll have side effects. Seroxat can also affect the way some other medicines work. These include:

- Medicines called **monoamine oxidase inhibitors** (MAOIs, including moclobemide) – see *Do not take Seroxat*, inside this leaflet
- Thioridazine or pimozide, which are **anti-psychotics** – see *Do not take Seroxat*, inside this leaflet
- Aspirin, ibuprofen or other medicines called NSAIDs (*non-steroidal anti-inflammatory drugs*) like celecoxib, etodolac and meloxicam, used for **pain and inflammation**
- Tramadol, a **painkiller**
- Medicines called *triptans*, such as sumatriptan, used to treat **migraine**
- Other **antidepressants** including other SSRIs, tryptophan and tricyclic antidepressants like clomipramine, nortriptyline and desipramine
- Medicines such as lithium, risperidone, perphenazine (called *anti-psychotics*) used to treat some **psychiatric conditions**
- A combination of fosamprenavir and ritonavir, which is used to treat **Human Immunodeficiency Virus (HIV) infection**
- St John's Wort, a herbal remedy for **depression**
- Phenobarbital, phenytoin or carbamazepine, used to treat **fits or epilepsy**
- Atomoxetine which is used to treat **attention deficit hyperactivity disorder (ADHD)**
- Procyclidine, used to relieve tremor, especially in **Parkinson's Disease**
- Warfarin or other medicines (called *anticoagulants*) used to **thin the blood**
- Propafenone, flecainide and medicines used to treat an **irregular heartbeat**
- Metoprolol, a beta-blocker used to treat **high blood pressure and heart problems**
- Rifampicin, used to treat **tuberculosis (TB) and leprosy**
- Linezolid, an **antibiotic**
- Tamoxifen, which is used to **treat breast cancer or fertility problems.**

► **If you are taking any of the medicines in this list**, and you have not already discussed these with your doctor, **go back to your doctor and ask what to do.** The dose may need to be changed or you may need to be given another medicine.

If you are taking any other medicines, including ones you have bought yourself, check with your doctor or pharmacist before taking Seroxat. They will know if it is safe for you to do so.

Seroxat and alcohol

Do not drink alcohol while you are taking Seroxat. Alcohol may make your symptoms or side effects worse.

Driving and using machinery

Possible side effects of Seroxat include dizziness, confusion or changes in eyesight. If you do get these side effects, do not drive or use machinery.

3. How to take your tablets

Take your tablets in the morning with food.

Swallow them with a drink of water.

Do not chew.

Seroxat tablets come in three strengths:

10 mg: White to pinkish white tablets, marked with "FC1" on one side and "GS" on the other

20 mg: White tablets, marked with "Seroxat 20"

30 mg: Blue tablets, marked with "Seroxat 30".

It is important to take your tablets as instructed by your doctor. The label will tell you how many tablets to take and how often. If you are unsure, ask your doctor or pharmacist.

Sometimes you may need to take more than one tablet or half a tablet. This table will show you how many tablets to take.

Dose	Number of tablets to take
10 mg	One white to pinkish white tablet or Half a white tablet
20 mg	One white tablet or Two white to pinkish white tablets
30 mg	One blue tablet or One-and-a-half white tablets or One white tablet and one white to pinkish white tablet
40 mg	Two white tablets or One blue tablet and one white to pinkish white tablet
50 mg	One blue tablet + One white tablet or Two-and-a-half white tablets or Two white tablets and one white to pinkish white tablet
60 mg	Two blue tablets or Three white tablets

Your doctor will advise you what dose to take when you first start taking Seroxat. Most people start to feel better after a couple of weeks. If you don't start to feel better after this time, talk to your doctor, who will advise you. He or she may decide to increase the dose gradually, 10 mg at a time, up to a maximum daily dose.

The usual doses for different conditions are set out in the table below.

	Starting dose	Recommended daily dose	Maximum daily dose
Depression	20 mg	20 mg	50 mg
Obsessive Compulsive Disorder (obsessions and compulsions)	20 mg	40 mg	60 mg
Panic Disorder (panic attacks)	10 mg	40 mg	60 mg
Social Anxiety Disorder (fear or avoidance of social situations)	20 mg	20 mg	50 mg
Post Traumatic Stress Disorder	20 mg	20 mg	50 mg
Generalised Anxiety Disorder	20 mg	20 mg	50 mg

Remember, your doctor will advise you on the daily dose you should take.

Your doctor will talk to you about how long you will need to keep taking your tablets. This may be for many months or even longer.

Older people

The maximum dose for people over 65 is 40 mg per day.

Patients with liver or kidney disease

If you have trouble with your liver or kidneys your doctor may decide that you should have a lower dose of Seroxat than usual. If you have severe liver or kidney disease the maximum dose is 20 mg per day.

What if you miss a dose?

Take your medicine at the same time every day.

If you do forget a dose, and you remember before you go to bed, take it straight away. Carry on as usual the next day.

If you only remember during the night, or the next day, leave out the missed dose. You may possibly get withdrawal effects, but these should go away after you take your next dose at the usual time.

What if you take too many tablets?

Never take more tablets than your doctor recommends. If you take too many Seroxat tablets (or someone else does), tell your doctor or a hospital straight away. Show them the pack of tablets.

What to do if you're feeling no better

Seroxat will not relieve your symptoms straight away - all antidepressants take time to work. Some people will start to feel better within a couple of weeks, but for others it may take a little longer. Some people taking antidepressants feel worse before feeling better. If you don't start to feel better after a couple of weeks, go back to your doctor who will advise you. Your doctor should ask to see you again a couple of weeks after you first start treatment. Tell your doctor if you haven't started to feel better.

4. Possible side effects

As with other medicines Seroxat can cause side effects, but not everybody gets them.

See the doctor if you get any of the following side effects during treatment.

You may need to contact your doctor or go to a hospital straight away.

Likely to affect up to 1 in every 100 people:

- **If you have unusual bruising or bleeding,** including vomiting blood or passing blood in your stools, **contact your doctor or go to a hospital straight away.**

- **If you find that you are not able to pass water, contact your doctor or go to a hospital straight away.**

Likely to affect up to 1 in every 1,000 people:

- **If you experience seizures (fits), contact your doctor or go to a hospital straight away.**

- **If you feel restless and feel like you can't sit or stand still,** you may have something called *akathisia*. Increasing your dose of Seroxat may make these feelings worse. If you feel like this, **contact your doctor.**

- **If you feel tired, weak or confused and have achy, stiff or uncoordinated muscles** this may be because your blood is low in sodium. If you have these symptoms, **contact your doctor.**

Likely to affect up to 1 in every 10,000 people:

- **Allergic reactions to Seroxat.**

If you develop a red and lumpy skin rash, swelling of the eyelids, face, lips, mouth or tongue, start to itch or have difficulty breathing or swallowing, **contact your doctor or go to a hospital straight away.**

- **If you have some or all of the following symptoms** you may have something called **serotonin syndrome**. The symptoms include: feeling confused, feeling restless, sweating, shaking, shivering, hallucinations (strange visions or sounds), sudden jerks of the muscles or a fast heartbeat. If you feel like this **contact your doctor.**

- **Acute glaucoma.**

If your eyes become painful and you develop blurred vision, **contact your doctor.**

Other possible side effects during treatment

Likely to affect more than 1 in 10 people:

- Feeling sick (*nausea*). Taking your medicine in the morning with food will reduce the chance of this happening.

- Change in sex drive or sexual function. For example, lack of orgasm and, in men, abnormal erection and ejaculation.

Likely to affect up to 1 in 10 people:

- Increases in the level of cholesterol in the blood

- Lack of appetite

- Not sleeping well (insomnia) or feeling sleepy

- Feeling dizzy or shaky (tremors)

- Headache

- Feeling agitated

- Blurred vision

- Yawning, dry mouth

- Diarrhoea or constipation

- Weight gain

- Feeling weak

- Sweating

Likely to affect up to 1 in every 100 people:

- A brief increase in blood pressure, or a brief decrease that may make you feel dizzy or faint when you stand up suddenly.

- A faster than normal heartbeat

- Lack of movement, stiffness, shaking or abnormal movements in the mouth and tongue

- Dilated pupils

- Skin rashes

- Feeling confused

- Having hallucinations (strange visions or sounds)

- An inability to urinate (urinary retention) or an uncontrollable, involuntary passing of urine (urinary incontinence).

Likely to affect up to 1 in every 1,000 people:

- Abnormal production of breast milk in men and women

- A slow heartbeat

- Effects on the liver showing up in blood tests of your liver function

- Panic attacks

- Overactive behaviour or thoughts (mania)

- Feeling detached from yourself (depersonalisation)

- Feeling anxious

- Pain in the joints or muscles.

Likely to affect up to 1 in every 10,000 people:

- Liver problems that make the skin or whites of the eyes go yellow

- Fluid or water retention which may cause swelling of the arms or legs

- Sensitivity to sunlight

- Painful erection of the penis that won't go away

- Unexpected bleeding, e.g. bleeding gums, blood in the urine or in vomit, or the appearance of unexpected bruises or broken blood vessels (broken veins)

- Some patients have developed buzzing, hissing, whistling, ringing or other persistent noise in the ears (tinnitus) when they take Seroxat.

▶ If you have any concerns while you are taking Seroxat, talk to your doctor or pharmacist who will be able to advise you.

5. Stopping Seroxat

Do not stop taking Seroxat until your doctor tells you to.

When stopping Seroxat, your doctor will help you to reduce your dose slowly over a number of weeks or months - this should help reduce the chance of withdrawal effects. One way of doing this is to gradually reduce the dose of Seroxat you take by 10 mg a week. Most people find that any symptoms on stopping Seroxat are mild and go away on their own within two weeks. For some people, these symptoms may be more severe, or go on for longer.

If you get withdrawal effects when you are coming off your tablets your doctor may decide that you should come off them more slowly. If you get severe withdrawal effects when you stop taking Seroxat, please see your doctor. He or she may ask you to start taking your tablets again and come off them more slowly. It may be easier for you to take Seroxat liquid during the time that you are coming off your medicine.

If you do get withdrawal effects, you will still be able to stop Seroxat.

Possible withdrawal effects when stopping treatment

Studies show that 3 in 10 patients notice one or more symptoms on stopping Seroxat. Some withdrawal effects on stopping occur more frequently than others.

Likely to affect up to 1 in 10 people:

- Feeling dizzy, unsteady or off-balance
- Feelings like pins and needles, burning sensations and (less commonly) electric shock sensations, including in the head
- Some patients have developed buzzing, hissing, whistling, ringing or other persistent noise in the ears (tinnitus) when they take Seroxat
- Sleep disturbances (vivid dreams, nightmares, inability to sleep)
- Feeling anxious
- Headaches.

Likely to affect up to 1 in every 100 people:

- Feeling sick (nausea)
- Sweating (including night sweats)
- Feeling restless or agitated
- Tremor (shakiness)
- Feeling confused or disorientated
- Diarrhoea (loose stools)
- Feeling emotional or irritable
- Visual disturbances
- Fluttering or pounding heartbeat (palpitations).

► **Please see your doctor if you are worried about withdrawal effects when stopping Seroxat.**

6. Children and adolescents under 18

Seroxat should not be used for children and adolescents under 18 years because it has not been proven to be an effective medicine for this age group. Also, patients under 18 have an increased risk of side effects such as suicidal thoughts and harming themselves when they take Seroxat. If your doctor has prescribed Seroxat for you (or your child) and you want to discuss this, please go back to your doctor.

In studies of Seroxat in under 18s, common side effects that affected less than 1 in 10 children/adolescents were: an increase in suicidal thoughts and suicide attempts, deliberately harming themselves, being hostile, aggressive or unfriendly, lack of appetite, shaking, abnormal sweating, hyperactivity (having too much energy), agitation, changing emotions (including crying and changes in mood). These studies also showed that the same symptoms affected children and adolescents taking sugar pills (*placebo*) instead of Seroxat, although these were seen less often.

Some patients in these studies of under 18s had withdrawal effects when they stopped taking Seroxat. These effects were mostly similar to those seen in adults after stopping Seroxat (see section 5, *Stopping Seroxat*, above). In addition, patients under 18 also commonly (affecting less than 1 in 10) experienced stomach ache, feeling nervous and changing emotions (including crying, changes in mood, trying to hurt themselves, thoughts of suicide and attempting suicide).

7. Looking after your tablets

- Keep your tablets in the pack with this leaflet.
- Do not store your tablets above 30°C.
- **Keep your tablets out of the reach and sight of children.**
- Do not take your tablets after the expiry date shown on the pack.
- If you are using half tablets, be careful to keep them safely in the pack.
- Never give these tablets to others, even if they have similar symptoms to yours.
- Finish all your tablets as the doctor tells you to.
- Keep this leaflet. You may need to read it again.

8. What Seroxat contains

The **active ingredient** in Seroxat film-coated tablets is paroxetine (as paroxetine hydrochloride hemihydrate).

The **inactive ingredients** are dibasic calcium phosphate dihydrate, sodium starch glycolate (Type A), magnesium stearate, hypromellose, macrogol 400, polysorbate 80, titanium dioxide (E171). The 30 mg tablet also contains indigo carmine (E132) and the 10 mg tablet also contains iron oxide red (E172). **Sodium content** of the 10 mg tablet is 0.1 mg, of the 20 mg tablet is 0.3 mg and of the 30 mg tablet, 0.4 mg.

Seroxat film-coated tablets are made by SmithKline Beecham Pharmaceuticals, Manor Royal, Crawley, West Sussex RH10 2QJ

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Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only)

Please be ready to give the following information:

Product name Seroxat 10 mg film-coated tablets
Seroxat 20 mg film-coated tablets
Seroxat 30 mg film-coated tablets

Reference number 10592/0218

This is a service provided by the Royal National Institute of Blind People.

Leaflet date: November 2008

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