

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a physician's prescription only

Seroxat

Film-Coated Tablets

Each film-coated tablet contains: paroxetine (as hydrochloride) 20 mg

For the list of the inactive and allergenic ingredients in the medicine, see section 2 - "Important information about some of the ingredients in the medicine" and section 6 "Additional Information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

Antidepressants and anti-anxiety medicines increase the risk of suicidal behavior and thoughts in patients up to the age of 25.

On starting treatment with the medicine, patients and their relatives should monitor any behavioral changes such as worsening of depression, suicidal thoughts, aggression, etc. If such changes should occur, refer immediately to the physician.

1. WHAT IS THE MEDICINE INTENDED FOR?

Seroxat is intended for treatment of adults with major/clinical depression and/or anxiety disorders. The anxiety disorders that Seroxat is used to treat are: obsessive compulsive disorder, panic disorder, social anxiety, post-traumatic stress disorder and generalised anxiety disorder.

Therapeutic group: *Selective serotonin reuptake inhibitors (SSRIs).*

It is not fully understood how Seroxat and other selective serotonin reuptake inhibitors work, but they may help by increasing the level of serotonin in the brain. Treating depression or anxiety disorders properly is important to help you feel better.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- **You are sensitive (allergic)** to paroxetine or to any of the additional ingredients contained in this medicine (listed in section 6).
- **You are taking medicines called monoamine oxidase inhibitors (MAOIs,** including moclobemide and methylthioninium chloride [methylene blue]) or have taken them at any time within the past two weeks. Your physician will advise you how you should begin taking Seroxat once you have stopped taking monoamine oxidase inhibitors.
- **You are taking an anti-psychotic** medicine called thioridazine or an anti-psychotic medicine called pimozide.

→ **If any of these apply to you,** tell your physician without taking Seroxat.

Special warnings regarding use of the medicine

Before beginning treatment with Seroxat, tell the physician if:

- You are taking any other medicines (see in section 2 “Drug interactions”)
- You are taking tamoxifen to treat breast cancer or fertility problems. Seroxat may make tamoxifen less effective, so your physician may recommend that you take a different antidepressant
- You have kidney, liver or heart trouble
- After an electrocardiogram (ECG), an abnormality of your heart tracing known as prolonged QT interval was found.
- You have a family history of QT prolongation, heart disease such as heart failure, low heart rate, or low potassium levels or low magnesium levels
- You have epilepsy or a history of fits or seizures
- You have ever had episodes of mania (overactive behavior and thoughts)
- You are receiving electro-convulsive therapy (ECT)

- You have a history of bleeding, or you are taking other medicines that may increase the risk of bleeding (these include medicines used to thin the blood such as warfarin, anti-psychotics such as perphenazine or clozapine, tricyclic antidepressants, medicines used for pain and inflammation called non-steroidal anti-inflammatory drugs (NSAIDs) such as: acetylsalicylic acid, ibuprofen, celecoxib, etodolac, diclofenac, meloxicam)
 - You have diabetes
 - You are on a low sodium diet
 - You have glaucoma (pressure in the eye)
 - You are pregnant or planning to become pregnant (see in section 2 “Pregnancy, breast-feeding and fertility”)
 - You are less than 18 years of age (see in section 2 “Children and adolescents under the age of 18”)
- **If any of these apply to you, and you have not yet consulted with your physician about them, go back to your physician and ask what you should do about taking Seroxat.**

Children and adolescents under the age of 18

Seroxat should not be used in children and adolescents under the age of 18.

Seroxat is not intended for use, and should not be used, to treat children and adolescents, since clinical studies have found a link between Seroxat and an increased risk of suicidal and hostile behavior.

The use of Seroxat in children under 7 years of age has not been tested.

Suicidal thoughts and worsening of your depression or anxiety disorder

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

You may be more likely to think like this:

- If you have previously had thoughts about harming yourself or committing suicide.

- If you are a **young adult**. Information from clinical trials has shown an increased risk of suicidal behavior in adults less than 25 years of age with psychiatric conditions treated with antidepressants.

→ If you have thoughts of harming or killing yourself at any time, **contact your physician 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 behavior.

Important side effects seen with Seroxat

Some patients who take Seroxat develop something called akathisia, where they **feel restless and feel like they cannot sit or stand still**. Other patients develop something called **serotonin syndrome, or neuroleptic malignant syndrome**, where they have some or all of the following symptoms: a strong feeling of nervousness or irritability, feeling confused, feeling restless, feeling hot, sweating, shaking, shivering, hallucinations (strange visions or sounds), muscle stiffness, sudden jerks of the muscles or a fast heartbeat. The severity can increase, leading to loss of consciousness. If you notice any of these symptoms, **contact your physician**. For more information on these or other side effects of Seroxat, see section 4.

Medicines such as Seroxat (referred to as *selective serotonin reuptake inhibitors, SSRIs*) may cause symptoms of sexual dysfunction (see section 4). In some cases, these symptoms have continued after stopping the treatment.

Drug interactions

Some medicines can affect the way Seroxat works, or increase the possibility that you will have side effects. Seroxat can also affect the way some other medicines work.

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the physician or pharmacist. Especially if you are taking:

- Medicines called **monoamine oxidase inhibitors** (MAOIs, including moclobemide and methylthionium chloride [methylene blue]) – see in section 2 “Do not use the medicine”.
- Medicines known to increase the risk of changes in the electrical activity of the heart (e.g. **the anti-psychotics** thioridazine or pimozide) - see section 2 “Do not use the medicine”.
- Acetylsalicylic acid (aspirin), ibuprofen or other medicines called NSAIDs (*non-steroidal anti-inflammatory drugs*) such as celecoxib, etodolac, diclofenac and meloxicam, used for treatment of **pain and inflammation**
- Tramadol, buprenorphine and pethidine, **painkillers**
- Buprenorphine combined with naloxone, substitution treatment for **opioid drug addiction**
- Medicines called *triptans*, such as sumatriptan, used to treat **migraine**
- Other **antidepressants** including other SSRIs and tricyclic antidepressants such as clomipramine, nortriptyline and desipramine
- A **dietary supplement** called tryptophan
- Mivacurium and suxamethonium (used in anesthesia)
- Medicines such as lithium, risperidone, perphenazine, clozapine (called *anti-psychotics*) used for treatment of certain **psychiatric conditions**
- Fentanyl, used in **anesthesia** or for treatment of **chronic pain**
- A combination of fosamprenavir and ritonavir, which is used to treat **human immunodeficiency virus (HIV) infection**
- Hypericum (St. John’s Wort), a herbal remedy for **depression**
- Phenobarbital, phenytoin, sodium valproate or carbamazepine, used for treatment of **fits or epilepsy**
- Atomoxetine used for treatment of **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 for treatment of an **irregular heartbeat**
- Metoprolol, a beta-blocker used for treatment of **high blood pressure and heart problems**

- Pravastatin, used for treatment of **high cholesterol**
 - Rifampicin, used for treatment of **tuberculosis (TB)** and **leprosy**
 - Linezolid, an **antibiotic**
 - Tamoxifen, which is used for **treatment of breast cancer** or **fertility problems**.
- **If you are taking or have recently taken any of the medicines in this list, and you have not yet consulted with your physician about them, go back to your physician and ask what to do.** The dosage may need to be adjusted or you may need to be given another medicine.

Antidepressants of the **SSRI** and **SNRI** group could cause serotonin syndrome (rarely) (see in section 2 “Important side effects seen with Seroxat” and section 4 “Side effects”).

This syndrome may occur more frequently if you are concomitantly taking other medicines acting on the central nervous system (see above). Inform the physician about any other medication that you are taking.

Use of the medicine and food

Taking Seroxat in the morning with food will reduce the likelihood of you feeling nauseous.

Use of the medicine and alcohol consumption

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

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your physician for advice before using this medicine. In babies whose mothers took Seroxat during the first 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 up to 2 in 100 babies in mothers who took Seroxat. You and your physician may decide that it is better for you to change to another

treatment or to gradually stop taking Seroxat while you are pregnant. However, depending on your circumstances, your physician may suggest that it is better for you to keep taking Seroxat.

Make sure that your physician or midwife knows that you are taking Seroxat. If you take Seroxat near the end of your pregnancy, there may be an increased risk of heavy vaginal bleeding shortly after birth, especially if you have a history of bleeding disorders. Your physician or midwife should be aware that you are taking Seroxat so they can advise you. When Seroxat is taken during pregnancy, particularly in the late stages of pregnancy, medicines like Seroxat may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (PPHN). In PPHN, the blood pressure in the blood vessels between the baby's heart and the lungs is too high. If you take Seroxat during the last 3 months of pregnancy, your newborn baby might also have other medical conditions, which usually begin during the first 24 hours after birth. Symptoms include:

- trouble with breathing
- a bluish skin or being too hot or too cold
- blue lips
- vomiting or feeding difficulties
- being very tired, not able to sleep or crying a lot
- stiff or floppy muscles
- tremors, jitters or fits
- exaggerated reflexes
- low blood sugar level.

→ If your baby experiences any of these symptoms at birth, or you are concerned about your baby's health, **refer to your physician for advice.**

Breast-feeding

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

Fertility

Animal studies have shown that paroxetine reduces sperm quality. Theoretically, this could affect fertility, but impact on human fertility has not yet been observed.

Driving and using machines

Possible side effects of Seroxat include dizziness, confusion, feeling sleepy or blurred vision. If you develop these side effects, do not drive or operate machinery.

Important information about some of the ingredients of the medicine

Seroxat contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, therefore it can be said that it is essentially 'sodium-free'.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the physician's instructions. Check with the physician or pharmacist if you are uncertain regarding the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the physician only. Sometimes you may need to take more than one tablet, or half a tablet.

Your physician will advise you what dose to take when you first start taking Seroxat. Most people start to feel better after two weeks. Tell your physician if you do not start to feel better after this time interval. He or she may decide to increase the dosage gradually, 10 mg at a time, up to a maximum daily dose.

Do not exceed the recommended dosage.

Take your tablets in the morning with food.

The tablets should be swallowed with water.

Do not crush/chew. You may halve the tablet to take a partial dose.

Your physician will instruct you as for how long you will need to keep taking the tablets. This may be for many months or even longer.

Older people

The maximum dose for people over the age of 65 years is 40 mg per day.

Patients with liver or kidney disease

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

If you accidentally have taken a higher dosage

Never take more tablets than your physician recommends. If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a physician or proceed to a hospital emergency room, and bring the package of the medicine with you.

Anyone who has taken an overdose of Seroxat may develop any of the symptoms listed in section 4 "Side effects", or the following symptoms: fever, uncontrolled muscle contraction.

If you forget to take the medicine

Take your medicine at the same time every day.

If you 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, omit the missed dose. You may possibly get withdrawal symptoms, but these should go away after you take your next dose at the usual time.

Do not take a double dose to make up for a forgotten dose.

What to do if you are not feeling any better

Seroxat will not relieve your symptoms straight away – all antidepressants take time to work. Some people will start to feel better within two weeks, but for others it may take a little longer. Some people taking antidepressants feel worse before feeling better. If you do not start to feel better after 2 weeks, go back to your physician for advice. Your physician will ask to see you again two weeks after you first start treatment. Tell your physician if you have not started to feel better.

If you stop taking the medicine

Adhere to the treatment regimen as recommended by the physician.

Even if there is an improvement in your health, **do not stop treatment with the medicine without consulting the physician.**

When you stop taking Seroxat, your physician will help you to reduce your dosage slowly over a number of weeks or months – this should help reduce the chance of withdrawal symptoms. One way of doing this is to gradually reduce your dosage of Seroxat 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 develop withdrawal symptoms when you stop taking your tablets, your physician may decide that stopping treatment should be done more slowly. If you get severe withdrawal symptoms when you stop taking Seroxat, please refer to your physician. Your physician may ask you to start taking your tablets again and then to stop treatment more slowly.

If you do develop withdrawal symptoms, you will still be able to stop taking Seroxat.

Possible withdrawal symptoms when stopping treatment

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

Common side effects

These may 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, and buzzing, hissing, whistling, ringing or other persistent noise in the ears (tinnitus)
- Sleep disturbances (vivid dreams, nightmares, inability to sleep)
- Feeling anxious
- Headaches.

Uncommon side effects

These may affect **up to 1 in 100** people:

- Nausea
- Sweating (including night sweats)
- Feeling restless or agitated
- Tremor
- Feeling confused or disorientated
- Diarrhoea (loose stools)
- Feeling emotional or irritable
- Visual disturbances
- Abnormal heart rate or palpitations.

→ **Please refer to your physician if you are worried about the withdrawal symptoms when stopping Seroxat.**

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the physician or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Seroxat may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Side effects are more likely to happen in the first few weeks of taking Seroxat.

Refer to the physician if you experience any of the following side effects during treatment

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

Uncommon side effects

These may affect up to 1 in 100 people:

- If you have unusual bruising or bleeding, including vomiting blood or passing blood in your stools, contact your physician or go to a hospital straight away.
- If you find that you are unable to urinate, contact your physician or go to a hospital straight away.

Rare side effects

These may affect up to 1 in 1,000 people:

- If you experience seizures (fits), contact your physician or go to a hospital straight away.
- If you feel restless and feel that you cannot sit or stand still, you may have an effect called *akathisia*. Increasing your dose of Seroxat may make these feelings worse. If you feel like this, contact your physician.
- If you feel tired, weak or confused and have achy, stiff or uncoordinated muscles this may be because your blood sodium level is low. If you experience these symptoms, contact your physician.

Very rare side effects

These may affect up to 1 in 10,000 people:

- Allergic reactions to Seroxat, which may be severe.

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 (shortness of breath) or swallowing and feel weak or lightheaded resulting in collapse or loss of consciousness, **contact your physician or go to a hospital straight away.**

- **If you have all or some of the following symptoms** you may have something called **serotonin syndrome or neuroleptic malignant syndrome**. The symptoms include: a strong feeling of nervousness or irritability, feeling confused, feeling restless, feeling hot, sweating, tremors, shivering, hallucinations (strange visions or sounds), muscle stiffness, sudden jerks of the muscles or a fast heartbeat. The severity can increase, leading to loss of consciousness. If you feel like this, **contact your physician.**
- **Acute glaucoma.**
If your eyes become painful and you develop blurred vision, **contact your physician.**

Side effects of unknown frequency (side effects whose frequency was not yet determined)

- Some people have had thoughts of harming or killing themselves while taking Seroxat or soon after stopping treatment (see “Suicidal thoughts and worsening of your depression or anxiety disorder” in section 2).
- Some people have experienced aggression while taking Seroxat.
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see “Pregnancy, breast-feeding and fertility” in section 2 for more information.

If you experience these side effects, contact your physician.

Additional side effects

Very common side effects

These may affect **more than 1 in 10** people:

- 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.

Common side effects

These may affect **up to 1 in 10** people:

- Increase in the level of cholesterol in the blood
- Lack of appetite
- Insomnia or feeling sleepy
- Abnormal dreams (including nightmares)
- Feeling dizzy or unstable (tremors)
- Headache
- Difficulty in concentrating
- Feeling agitated
- Feeling unusually weak
- Blurred vision
- Yawning, dry mouth
- Diarrhoea or constipation
- Vomiting
- Weight gain
- Sweating.

Uncommon side effects

These may affect **up to 1 in 100** people:

- A brief increase or decrease in blood pressure, which 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
- Itching
- Feeling confused
- Having hallucinations (strange visions or sounds)
- An inability to urinate (urinary retention) or an uncontrollable, involuntary passing of urine (urinary incontinence).

- If you are a diabetic patient you may notice a lack of control of your blood sugar levels while taking Seroxat. Refer to your physician about adjusting the dosage of your insulin or diabetes medications
- Reduction in white blood cell count.

Rare side effects

These may affect **up to 1 in 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
- Overexpression of behavior or thoughts (mania)
- Feeling detached from yourself (depersonalization)
- Feeling anxious
- Irresistible urge to move the legs (restless legs syndrome)
- Pain in the joints or muscles
- Increase in a hormone called prolactin in the blood
- Menstrual period disorders (including heavy or irregular periods, bleeding between periods and absence or delay of periods).

Very rare side effects

These may affect **up to 1 in 10,000** people:

- Skin rash, which may form blisters, and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) called erythema multiforme
- A widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome)
- A widespread rash with blisters and peeling skin on much of the body surface (toxic epidermal necrolysis)
- Liver problems that make the skin or whites of the eyes yellow
- Syndrome of inappropriate antidiuretic hormone production (SIADH), which is a condition in which the body develops an excess of water and a decrease in sodium (salt) concentration, as a result of improper chemical signals.

Patients with SIADH may become severely sick or may have no symptoms at all

- Fluid or water retention (which may cause swelling of the arms or legs)
- Sensitivity to sunlight
- Painful erection of the penis that does not go away
- Low blood platelet count.

Side effects of unknown frequency (side effects whose frequency was not yet determined)

- Inflammation of the colon (causing diarrhoea)
- Teeth grinding.

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

An increased risk of bone fractures has been observed in patients taking this type of medicine.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the physician.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il/>

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine and every other medicine should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.

- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- Store in the original packaging to protect from light.
- **If you use half-tablets, make sure to store them safely inside the package.**
- Do not discard medicines in the wastewater or household waste bin. Ask the pharmacist how to dispose of medicines that are no longer in use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

- In addition to the active ingredient, the medicine also contains:
 - In the tablet core:** dibasic calcium phosphate dihydrate (E341), sodium starch glycolate (Type A), magnesium stearate (E470b).
 - In the tablet coating:** hypromellose (E464), titanium dioxide (E171), macrogol 400, polysorbate 80 (E433).
- What the medicine looks like and what are the contents of the package:

Seroxat 20 mg film-coated tablets are white, oval-shaped tablets, marked '20' on one side, and with a score line on the other side. Each pack of Seroxat contains a child-resistant blister with the amount of either 10, 20 or 30 tablets.

Not all package sizes may be marketed.
- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: GlaxoSmithKline Trading Services Limited, Dublin, Ireland.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 131-27-27592.

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