



Seroxat CR

12.5 mg & 25 mg controlled release film coated tablets

Paroxetine hydrochloride

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Seroxat CR

Paroxetine Controlled Release Tablets

Read this carefully before you start taking **Seroxat CR** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Seroxat CR**.

What is Seroxat CR used for?

- Seroxat CR is used in adults (18 years of age and older) to relieve symptoms of:
 - **Major Depressive Disorder** (feeling sad, a change in appetite or weight, difficulty concentrating or sleeping, feeling tired, headaches, unexplained aches and pain).
 - **Panic Disorder (with or without agoraphobia)** (panic attacks).
 - **Social Phobia (social anxiety disorder)** (avoidance and/or fear of social situations).
 - **Premenstrual Dysphoric Disorder (PMDD)** (episodes of major depression, severe mood changes, anxiety, irritability, physical pain, difficulty doing day to day tasks before your period).
- Seroxat CR is not for use in children under 18 years of age.

How does Seroxat CR work?

Seroxat CR belongs to the group of medicines called selective serotonin reuptake inhibitors (SSRIs). Seroxat CR is thought to work by increasing the levels of a chemical in the brain called serotonin (5-hydroxytryptamine). This helps to relieve your symptoms of depression, panic disorder, social phobia or premenstrual dysphoric disorder. Seroxat CR may take a number of weeks to work.

What are the ingredients in Seroxat CR?

Medicinal ingredient: Paroxetine hydrochloride.
 Non-medicinal ingredients: Colloidal silicon dioxide, glyceryl behenate, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, methacrylic acid copolymer type C, polyethylene glycol, polysorbate 80, polyvinylpyrrolidone, sodium lauryl sulphate, talc, titanium dioxide and triethyl citrate. In addition, each tablet also includes:

- 12.5 mg Tablet: D&C yellow No. 10 aluminium lake, FD&C yellow No. 6 aluminium lake and yellow ferric oxide.
- 25 mg Tablet: D&C red No. 30 aluminium lake and red ferric oxide.

Seroxat CR comes in the following dosage forms:

Controlled Release Tablets: 12.5 mg and 25 mg of paroxetine (as paroxetine hydrochloride).

Do not use Seroxat CR if:

- you are allergic to paroxetine hydrochloride or to any of the non-medicinal ingredients in Seroxat CR (see "What are the ingredients in Seroxat CR").
 - you are taking or have recently taken in the last 14 days medicines called monoamine oxidase inhibitors (MAOI) including linezolid (an antibiotic) or methylene blue (a dye injected into a vein during surgery, x-rays or other imaging procedures).
 - you are taking or have recently taken thioridazine or pimozide. These medicines are used to treat mental health problems.
- Ask your healthcare provider or pharmacist if you are not sure if you take a MAOI or one of these medicines, including the antibiotic linezolid or intravenous methylene blue. Do not start taking a MAOI or thioridazine or pimozide for at least 14 days after you stop treatment with Seroxat CR.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Seroxat CR. Talk about any health conditions or problems you may have, including if you:

- have epilepsy or a history of seizures.
- have a history of liver or kidney problems.
- have heart problems.
- have a history or family history of mania/hypomania or bipolar disorder.
- have depression or other mental health disorders.
- have high cholesterol.
- have low levels of sodium in your blood.
- have had a recent bone fracture or were told you have osteoporosis or risk factors for osteoporosis.
- have a bleeding disorder or have been told that you have low platelets.
- are pregnant or planning to become pregnant.
- are breast feeding or planning to breast feed.
- have a history of alcohol or drug abuse.
- have ever had any allergic reactions to medications, food, etc.
- are taking oral contraceptives and are being prescribed Seroxat CR for Premenstrual Dysphoric Disorder.
- are allergic to azo dye (FD&C Yellow No. 6 aluminium lake). The 12.5 mg tablet contains an azo dye component.
- have an eye condition known as narrow angles (the iris and cornea of the eye are closer than normal).

Other warnings you should know about:

Pregnancy: Only take Seroxat CR during pregnancy if you and your healthcare professional have discussed the risks and have decided that you should. If you take Seroxat CR near the end of your pregnancy, you are at a higher risk of heavy vaginal bleeding shortly after birth. If you become pregnant while taking Seroxat CR, tell your healthcare professional **right away**.

Effects on newborns: In some cases, babies born to a mother taking Seroxat CR during pregnancy may require hospitalization, breathing support and tube feeding. Be ready to seek medical help for your newborn if they:

- Have trouble breathing or feeding.
- Have muscle stiffness, or floppy muscles (like a rag doll).
- Have seizures (fits).
- Are shaking (jitteriness).
- Are constantly crying.

If you take Seroxat CR:

- During early pregnancy, there is a possible slight increased risk that your newborn may have birth defects, particularly a heart defect.
- During late pregnancy, your newborn may be at risk of having a serious lung condition called Persistent Pulmonary Hypertension of the Newborn (PPHN), which causes breathing problems.

Fertility and sexual function: Taking medicines like Seroxat CR may increase your risk of having sexual problems. This may continue after Seroxat CR has been discontinued, including for months or years afterwards in some cases. Tell your healthcare professional if you experience symptoms such as a decrease in sexual desire, performance or satisfaction. Medicines like Seroxat CR may affect sperm quality. Fertility in some men may be reduced while taking Seroxat CR.

Falls and fractures: Seroxat CR can cause you to feel dizzy or lightheaded and can affect your balance. This increases your risk of falling. In addition Seroxat CR may increase your risk of breaking a bone if you are:

- elderly,
- have osteoporosis, or
- have other major risk factors for breaking a bone.

You should take extra care to avoid falls especially if you get dizzy or have low blood pressure.

Driving and using machines: Seroxat CR may make you feel sleepy. Avoid driving a vehicle or using machinery until you know how it affects you.

Angle-closure glaucoma: Seroxat CR can cause an acute attack of glaucoma. Having your eyes examined before you take Seroxat CR could help identify if you are at risk of having angle-closure glaucoma. Seek immediate medical attention if you experience:

- eye pain,
- changes in vision,
- swelling or redness in or around the eye.

Cholesterol and blood tests: Seroxat CR can cause abnormal blood test results, including elevated levels of cholesterol. Your healthcare professional will decide when to perform blood tests and will interpret the results.

Do NOT stop taking Seroxat CR without talking to your healthcare professional first. If stopped abruptly, Seroxat CR may cause unwanted side effects such as:

- light-headedness,
- nausea and vomiting,
- agitation/restlessness,
- anxiety,
- sweating,
- headache,
- sleep disturbance,
- electric shock sensations,
- tinnitus (buzzing, hissing, whistling, ringing or other persistent noise in the ears).

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Serious Drug Interactions

Do not take Seroxat CR if you are taking or have recently taken any of the following drugs as you may have serious side effects:

- monoamine oxidase inhibitors (MAOIs) such as the antibiotic linezolid and the intravenous dye methylene blue.
- thioridazine (typically used to treat schizophrenia and psychosis).
- pimozide (typically used to manage Tourette's syndrome).

Wait **14 days** after you stop taking a MAOI, or thioridazine, or pimozide before starting Seroxat CR. If you are unsure, ask your healthcare professional.

The following may also interact with Seroxat CR.

- other antidepressants, such as SSRIs, SNRIs, and certain tricyclics.
- other drugs that affect serotonin such as, lithium (used to treat bipolar depression), linezolid (antibiotic), tramadol (used to treat pain), tryptophan (used to treat anxiety or used as a sleep aid), and triptans (used to treat migraines).
- drugs used to prevent fits or treat epilepsy (anticonvulsants), such as carbamazepine, phenytoin, sodium valproate.
- drugs used to treat pain, such as fentanyl (used in anaesthesia or to treat chronic pain), tramadol, tapentadol, meperidine, methadone, and pentazocine.
- drugs used to treat breast cancer or fertility problems, such as tamoxifen.
- drugs used to treat patients with irregular heart beats (arrhythmias).
- drugs used to treat schizophrenia.
- drugs used to treat Human Immunodeficiency Virus (HIV) infection, such as a combination of fosamprenavir and ritonavir.
- drugs used to treat Parkinson's Disease or other movement disorders, such as procyclidine.
- drugs used to treat high blood pressure and angina, such as metoprolol.
- drugs which may affect blood clotting and increase bleeding, such as oral anti-coagulants (e.g. warfarin, dabigatran), acetylsalicylic acid (e.g. aspirin) and other non-steroidal anti-inflammatory drugs (e.g. ibuprofen).
- drugs that affect the central nervous system, such as haloperidol, amylbarbitone, and oxazepam.
- drugs used to treat cough, such as dextromethorphan.
- drugs to treat heartburn, such as cimetidine.
- drugs to treat respiratory diseases (chronic obstructive pulmonary disease (COPD) and asthma), such as theophylline.
- any natural herbal products (e.g. St. John's Wort).
- alcohol.

How to take Seroxat CR:

- It is very important that you take Seroxat CR exactly as your healthcare professional has instructed.
- Take your tablets in the morning, with or without food.
- Swallow tablet(s) whole with water. Do not chew or crush tablet(s).
- You should continue to take your medicine even if you do not feel better, as it may take a number of weeks for your medicine to work.
- Keep taking your tablets, as instructed, until your healthcare professional tells you to stop.
- Talk to your healthcare professional before you stop taking your medication on your own.

Remember: This medicine has been prescribed only for you. Do not give it to anybody else, as they may experience undesirable effects, which may be serious.

Usual Dose:

The starting dose of Seroxat CR depends on your illness and current health. It is usually 12.5 mg or 25 mg once a day in the morning. Your healthcare professional may gradually increase your dose to help control your symptoms.

Overdose:

If you think you, or a person you are caring for, have taken too much Seroxat CR, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to take your tablet in the morning, take it as soon as possible, unless it is too close to the time of the next dose. Take your next dose at the normal time the next morning, then carry on as before. Do not try to make up for a missed dose by taking a double dose the next time.

What are possible side effects from using Seroxat CR?

These are not all the possible side effects you may have when taking Seroxat CR. If you experience any side effects not listed here, tell your healthcare professional.

- Side effects may include:
- blurred vision
 - constipation
 - diarrhoea
 - dizziness
 - drowsiness
 - dry mouth
 - feeling agitated
 - headache
 - loss of appetite
 - nausea/vomiting
 - nervousness
 - sexual problems (decreases in sexual desire, performance and satisfaction, may also lead to further decreases, which may continue after the drug is stopped)
 - skin rash or hives alone
 - sleep disturbances (abnormal dreams including nightmares)
 - sweating
 - tremor (shaking)
 - weakness
 - weight gain.



Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNCOMMON			
Dilated pupils		✓	
Gastrointestinal bleeding (bleeding in the stomach or bowels) vomiting blood or passing black, tarry stool, blood in stool			✓
Hallucinations: seeing and hearing things that are really not there		✓	
Hypotension (low blood pressure): dizziness, light-headedness or fainting when standing up from a sitting down or lying position		✓	
Oedema: swelling of hands, ankles or feet		✓	
Seizures (fits): uncontrollable shaking with or without loss of consciousness			✓
Urinary retention (inability to urinate or empty or loss of control of the bladder): pain		✓	
RARE			
Thrombocytopenia (low platelets): bruising or unusual bleeding from the skin or other areas, bleeding for longer than usual if you hurt yourself, fatigue and weakness		✓	
Urinary incontinence (involuntary loss of urine)		✓	
VERY RARE			
Severe allergic reactions: red and lumpy skin rash, itching, hives, swelling of the lips, face, tongue, throat, trouble breathing, wheezing, shortness of breath, skin rashes, collapse or loss of consciousness			✓
Severe skin reactions (Stevens-Johnson syndrome, toxic epidermal necrolysis, and erythema multiforme): any combination of itchy skin rash, redness, blistering and peeling of the skin and/or inside of the lips, eyes, mouth, nasal passages or genitals, accompanied by fever, chills, headache, cough, body aches or swollen glands, joint pain, yellowing of the skin or eyes, dark urine.			✓
UNKNOWN FREQUENCY			
Akathisia: (a type of movement disorder): feeling restless, unable to sit or stand still.		✓	
Angle-closure glaucoma (eye condition that can cause damage to the optic nerve): increased pressure in your eyes, sudden eye pain, eye and head pain, swelling or redness in or around the eye, hazy or blurred vision, sudden loss of sight.			✓
Changes in feelings or behaviour: anger, anxiety or violent thoughts.		✓	
Hyponatremia (low sodium level in blood): symptoms of tiredness, weakness, muscle twitching, confusion combined with achy, stiff or uncoordinated muscles.		✓	
Increase in the hormone prolactin: In women: breast discomfort, leakage of milk from the breasts, missed periods, or other problems with your menstrual cycle. In men: decreased body and facial hair, breast swelling, leakage of milk from the breasts, difficulty in getting or maintaining erections, or other sexual dysfunction.			✓
Liver disorder: symptoms include nausea, vomiting, loss of appetite combined with itching, yellowing of the skin or eyes, dark urine.		✓	
Mania: elevated or irritable mood, decreased need for sleep, racing thoughts, overactive behaviour and thoughts.		✓	
Menstrual period disorders: including heavy periods, bleeding between periods and absence of periods.		✓	
Photosensitivity (sensitivity to sunlight): itchy, red skin when exposed to sunlight.	✓		
Restless legs syndrome: irresistible urge to move the legs.		✓	
Serotonin toxicity (also known as serotonin syndrome) and neuroleptic malignant syndrome (NMS): a combination of most or all of the following: confusion, restlessness, sweating, shaking, shivering, high fever, hallucinations, sudden jerking of the muscles, muscle stiffness, feeling very agitated or irritable, fast heartbeat. The severity can increase, leading to loss of consciousness.			✓
Thoughts or actions about hurting or killing yourself.			✓
Uncontrollable movements of the body or face.		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effect not listed in this leaflet. To report Product Complaints or Adverse Event/s associated with the use of GSK product/s, please contact us via: gulf.safety@gsk.com. By reporting side effects you can help provide more information on the safety of this medicine.

Storage:

- Store between 15°C to 25 °C.
- Keep container tightly closed.
- If your healthcare professional tells you to stop taking SEROXAT CR, please return any leftover medicine to your pharmacist.
- You may need to read this package insert again. Please keep this package insert until you have finished your medicine.
- Keep out of reach and sight of children.

This leaflet was prepared by GlaxoSmithKline Inc.

Last Revised: September 22, 2022

Packed by **Pharmaline** - Lebanon

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This is a Medicament

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers,
 Union of Arab Pharmacists.

DIMENSIONS 170 x 690 mm
COLOR BLACK, PANTONE ORANGE 158

Date of Issue 27 - 09 - 2023
Description SEROXAT CR 12,5 & 25 MG PIL (170 x 690 mm)

	GSK Approval		PHARMALINE Approval	
	Regulatory (Local)	Quality Assurance	Regulatory	Quality Assurance
Name				
Signature				
Date				