

SEROXAT CR TABLET

Paroxetine hydrochloride hemihydrate (12.5 mg, 25mg)

What is in this leaflet

1. What SEROXAT CR is used for
2. How SEROXAT CR works
3. Before you use SEROXAT CR
4. How to use SEROXAT CR
5. While you are using it
6. Side Effects
7. Storage and Disposal of SEROXAT CR
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of RiMUP Revision

What SEROXAT CR is used for

In adults aged 18 years and over, SEROXAT CR is used to treat:

- Depression
- A severe form of premenstrual syndrome (*premenstrual dysphoric disorder*), symptoms include depression, severe mood changes, irritability
- Panic attacks, including those caused by a fear of open spaces (*agoraphobia*)
- Anxiety caused by situations such as socialising or performance

These conditions can occur when the amount of a substance called serotonin in the brain is reduced.

How SEROXAT CR works

The active ingredient in SEROXAT CR is paroxetine which belongs to a group of medicines called SSRIs (*selective serotonin reuptake inhibitors*).

Paroxetine works by increasing serotonin levels in the brain.

Before you use SEROXAT CR

- When you must not use it

Do not use SEROXAT CR:

- If you are allergic (*hypersensitive*) to paroxetine or any other ingredients of SEROXAT CR (see section **Product Description**).
- If you are taking or have recently taken (within the last two weeks) medicines for depression called monoamine oxidase inhibitors (MAOIs).
- If you are taking or have recently taken (within the last two weeks) an antibiotic called linezolid.

- If you are taking or have recently taken (within the last two weeks) a medicine called methylthioninium chloride (methylene blue).
- If you are taking medicines called thioridazine or pimozide (usually used to treat schizophrenia).

If you think any of these apply to you, don't take SEROXAT CR until you have checked with your doctor.

- Before you start to use it

Before you take SEROXAT CR your doctor needs to know:

- If you have ever had episodes of hyperactivity, elation and irritability (*mania*)
- If you have ever had periods of mania alternating with periods of depression (*bipolar mood disorder*)
- If you have kidney or liver disease
- If you have heart disease
- If your heart tracing (electrocardiogram/ECG) has an abnormality known as prolonged QT interval or you are taking medicines that may affect the QT interval in the ECG
- If you have epilepsy
- If you suffer from glaucoma (a condition caused by raised pressure in the eye)
- If you are receiving electroconvulsive treatment (ECT) (usually used for severe depression)
- If you have a history of bleeding problems

Check with your doctor if you think any of these may apply to you. Your doctor will decide whether SEROXAT CR is suitable for you, or if you need extra check-ups.

Pregnancy and breastfeeding

SEROXAT CR is not usually recommended for use during pregnancy. If you are pregnant or think you could be, or if you are planning to become pregnant, speak to your doctor immediately. Your doctor will consider the benefit to you and the risk to your

baby of taking SEROXAT CR while you are pregnant.

If you take SEROXAT CR near the end of your pregnancy there may be an increased risk of excessive vaginal bleeding shortly after birth, especially if you have a history of bleeding disorders. Your doctor or midwife should be aware that you are taking SEROXAT CR so they can advise you.

If SEROXAT CR is used until delivery, the following symptoms have been reported in babies immediately or within the first 24 hours after birth. Again, it is not known if these symptoms are due to the use of SEROXAT CR. The symptoms are:

- Trouble with breathing
- A blue-ish skin or being too hot or cold
- Vomiting or not feeding properly
- Being very tired, not able to sleep or constant crying
- Stiff or floppy muscles
- Tremors, jitters or fits

If your baby has any of these symptoms when it is born, or you are concerned about your baby's health, contact your doctor or midwife for advice.

The ingredients in SEROXAT CR can pass into breast milk. If you are breast-feeding, you must check with your doctor before you take SEROXAT CR.

Children and adolescents aged under 18 years

SEROXAT CR is not recommended for people aged under 18. The effectiveness of SEROXAT CR has not been demonstrated in this age group.

Medicines used to treat depression and other mental health problems may increase the risk of suicidal thoughts and behavior in children and adolescents aged under 18 years. There is no information on the long term safety of SEROXAT CR in this age group.

- **Taking other medicines**

Before you take SEROXAT CR your doctor needs to know if you are taking medicines that increase your risk of bleeding.

Tell your doctor or pharmacist if you're taking any other medicines, if you've taken any recently, or if you start taking new ones. This includes herbal medicines and other medicines you bought without a prescription.

Some medicines must not be taken with SEROXAT CR. Taking SEROXAT CR with medicines which may raise serotonin levels in the brain, can increase your risk of side effects. These include:

- Triptans (used to treat migraine)
- Tramadol (used to treat pain)
- Tryptophan or SSRIs (used to treat depression)
- St. John's Wort (a herbal remedy used to treat depression)
- Lithium (used to treat some mental health problems)
- Fentanyl (used in anaesthesia or to treat chronic pain)

Tell a doctor or pharmacist if you are taking any of these. You should be closely monitored while you are taking them with SEROXAT CR.

Some medicines can affect how SEROXAT CR works. SEROXAT CR can also affect how some other medicines work. These include:

- Carbamazepine, phenobarbital and phenytoin which are usually used to treat fits (seizures or epilepsy)
- Mivacurium and suxamethonium (used in anaesthesia)
- Rifampicin (used to treat tuberculosis)
- Fosamprenavir and ritonavir (used to treat HIV)
- Procyclidine (used to treat Parkinson's disease)
- Amitriptyline, nortriptyline, imipramine and desipramine (used to treat depression)
- Perphenazine and risperidone (used to treat some mental health problems)
- Atomoxetine (used to treat attention deficit hyperactive disorder, ADHD)
- Propafenone and flecainide (used to treat an irregular heart beat)

- Metoprolol (used to treat high blood pressure)
- Tamoxifen (used to treat or prevent breast cancer or fertility problems)

Tell a doctor or pharmacist if you are taking any of these. Your doctor may decide to adjust your dose. Other medicines not listed above may also interact with SEROXAT CR.

How to use SEROXAT CR

- **How much to use**

The starting dose of SEROXAT CR depends on your illness. It is usually 12.5 mg or 25 mg once a day. Your doctor may gradually increase your dose to help control your symptoms.

If you are aged over 65, or have liver or kidney problems, the maximum dose may be reduced.

- **When to use it**

Swallow your SEROXAT CR tablets whole with some water. Don't chew, crush or split the tablets – if you do, there is a danger you could overdose, because the medicine may be released into your body too quickly.

Take SEROXAT CR in the morning. You can take SEROXAT CR with or without food.

- **How long to use it**

The duration of treatment will depend on your illness. Whilst people usually feel some improvement within two weeks or so, it can take longer for the medicine to have its full effect.

Even after you start to feel better, it is important to keep taking SEROXAT CR for as long as your doctor recommends to help prevent symptoms from returning. This can be several months after recovery from depression and may even be longer for panic disorder.

- **If you forget to use it**

Don't take an extra dose to make up for a missed dose. Just take your next dose at the usual time. If you are not sure what to do, ask your doctor or pharmacist.

- **If you use too much (overdose)**

If you take too much SEROXAT CR you are more likely to get side effects. Taking too much SEROXAT CR may also cause blood pressure changes, uncontrollable muscle contractions, anxiety, a high temperature and a fast heart beat.

If you take too much SEROXAT CR, contact your doctor or go to the Emergency Department of your nearest hospital. If possible, show them the SEROXAT CR pack.

While you are using SEROXAT CR

- **Things you must do**

Always take SEROXAT CR exactly as your doctor has told you to. Check with your doctor or pharmacist if you're not sure.

- **Things you must not do**

Don't stop taking SEROXAT CR without talking to your doctor first. Your dose needs to be reduced gradually, otherwise you may get unwanted effects (see section **Side effects**).

- **Things to be careful of**

Suicidal thoughts or thoughts of harming yourself

If you are depressed, you may sometimes have suicidal thoughts or thoughts of harming yourself. Since medicines like SEROXAT CR take time to work (usually about 2 weeks, but sometimes longer), suicidal thoughts or thoughts of harming yourself may continue or increase, particularly when you start taking SEROXAT CR.

You may be more likely to think like this if you:

- Are a young adult
 - Have previously had thoughts of this nature
 - Have recently had a change in dose
- If you have distressing thoughts or experiences, or if you notice that you feel worse or develop new symptoms while you're taking SEROXAT CR, 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, and ask them to read this leaflet. You

might ask them to tell you if they think your depression is getting worse, or if they are worried about changes in your behavior.

Medicines used to treat some mental health problems can cause a feeling of inner restlessness and the urge to move (*akathisia*). This is a rare side effect of SEROXAT CR, and is most likely to occur in the first few weeks of treatment. Tell your doctor as soon as possible if you get these symptoms.

SEROXAT CR may cause symptoms of sexual dysfunctions. In some cases, these symptoms have continued after stopping treatment.

There is an increased risk of bone fracture (breaking a bone) in people taking medicines like SEROXAT CR. This risk is greatest during the early stages of treatment.

SEROXAT CR 12.5 mg tablets only
SEROXAT CR 12.5 mg tablet coating (Opadry Yellow: 15B120039) contains the colouring agent Sunset Yellow Lake (FD&C Yellow No. 6 aluminium lake), an azo dye which may cause allergic-type reactions.

Fertility

Medicines like SEROXAT CR may affect your sperm. Fertility may be reduced in some men during treatment with SEROXAT CR.

Driving and using machines

SEROXAT CR can make you feel dizzy or confused and can affect your eyesight. Don't drive or use machines if you get side effects such as these. It is recommended that you don't drink alcohol while you're taking SEROXAT CR.

Side Effects

Like all medicines, SEROXAT CR can cause side effects, but not everybody gets them.

Symptoms seen when SEROXAT CR is stopped:

Stopping medicines used for treating mental health problems often causes

unwanted symptoms. The symptoms are more likely to occur in the first few days of stopping treatment and usually go away within a few weeks.

If you need to stop taking SEROXAT CR, your doctor may reduce your dose gradually. This should help to reduce any effects and their severity.

Common symptoms seen when SEROXAT CR is stopped:

These may affect up to 1 in 10 people:

- Dizziness
- Feelings like pins and needles, electric shock sensations and persistent noise in the ears (*tinnitus*)
- Sleep disturbances including intense dreams
- Feeling anxious
- Headache

Uncommon symptoms seen when SEROXAT CR is stopped:

These may affect up to 1 in 100 people:

- Feeling restless or agitated
- Feeling sick (nausea)
- Tremors
- Feeling confused
- Sweating
- Diarrhoea

Talk to your doctor if these symptoms become severe or troublesome.

Conditions to look out for:

Severe allergic reactions. These are very rare in people SEROXAT CR. Signs include:

- Raised and itchy rash (hives)
- Swelling, sometimes of the face or mouth (angioedema), causing difficulty in breathing
- Collapse or loss of consciousness

Contact a doctor immediately if you get these symptoms. Stop taking SEROXAT CR.

Serotonin Syndrome and Neuroleptic Malignant Syndrome

These are very rare side effects of SEROXAT CR.

The symptoms of both Serotonin Syndrome and Neuroleptic Malignant Syndrome are similar. Usually more than one of the following symptoms will occur:

- Tremor

- Sudden uncontrollable jerky movements
- Muscle stiffness
- Difficulty sitting still
- Feeling very agitated or irritable
- Feeling hot or sweaty
- Increase in heart rate

The severity can increase, leading to loss of consciousness.

Contact your doctor urgently if you get these symptoms.

Tell your doctor if you notice any of the following and they worry you:

Very common side effects

These may affect more than 1 in 10 people:

- Feeling sick (nausea)
- A change in sex drive or sexual function

Common side effects

These may affect up to 1 in 10 people:

- Decreased appetite
- Difficulty in sleeping (insomnia) or feeling drowsy
- Feeling agitated
- Feeling dizzy
- Tremors
- Headache
- Blurred vision
- Yawning
- Dry mouth
- Constipation
- Diarrhoea
- Being sick (vomiting)
- Sweating
- Feeling weak
- Abnormal dreams (including nightmares)
- Weight gain

Common side effects that may show up in blood tests:

- Increase in cholesterol

Uncommon side effects

These may affect up to 1 in 100 people:

- Bruising or unusual bleeding mainly of the skin and moist areas such as the mouth
- Feeling confused
- Seeing or hearing things that are not really there (*hallucinations*)

- Involuntary muscle movements of the face, twisting movements of the body, arms and legs, tremor
- Dilated pupils
- A faster than normal heart beat
- Low blood pressure (may cause dizziness, light-headedness or fainting when standing up from a sitting or lying position)
- Skin rashes
- Unable to pass urine or loss of control of the bladder

Rare side effects

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

- A feeling of restlessness and difficulty sitting or standing still
- Episodes of hyperactivity, elation and irritability
- Fits
- Irresistible urge to move the legs
- Abnormal secretion of breast milk in men and women
- Menstrual disorders

Very rare side effects

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

- Skin rash, which may blister, and looks like small targets (central dark spots surround by a paler area, with a dark ring around the edge)
- A widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals
- A widespread rash with blisters and skin peeling on much of the body surface
- water retention
- Glaucoma (a condition caused by raised pressure in the eye)
- Bleeding in the digestive system (passing blood in the stools or black stools)
- Yellowing of the skin and the whites of the eyes (*jaundice*)
- Increased sensitivity of the skin to sunlight
- Swelling of hands, ankles or feet

Other side effects not listed above may occur in some patients. Tell your doctor and pharmacist if you notice anything else that is making you feel unwell.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of SEROXAT CR

- Storage

Keep out of the reach and sight of children. Do not take SEROXAT CR after the expiry date shown on the pack. Store it in its original packaging. Store below 30°C.

- Disposal

If you have unwanted SEROXAT CR tablets, don't dispose of them in your waste water or household rubbish. Ask your pharmacist how to dispose of medicines no longer required. This will help to protect the environment.

Product Description

- What it looks like

12.5 mg controlled-release tablets:
Yellow, round, biconvex tablets with GSK engraved on one side and 12.5 on the other side.

25 mg controlled-release tablets:
Pink, round, biconvex tablets with GSK engraved on one side and 25 on the other side.

- Ingredients

- Active ingredient(s)
12.5 mg and 25 mg contain paroxetine hydrochloride equivalent to 12.5 mg and 25 mg paroxetine free base, respectively.

- Inactive ingredient(s)
Tablet cores: Hypromellose; Povidone; Lactose Monohydrate; Magnesium Stearate; Colloidal silicon dioxide; Glyceryl Dibehenate and the following colourants: Yellow Ferric Oxide (12.5mg tablets) and Red Ferric Oxide (25 mg tablets).

Tablet coating: Methacrylic Acid and Ethyl Acrylate Copolymer Dispersion; Talc; Triethyl citrate, Opadry Yellow, 15B120039 (12.5 mg tablets, includes the colouring agent Sunset Yellow Lake

(FD&C Yellow No. 6 aluminium lake)), Opadry Pink, Y-1-1262 (25 mg tablets).

- MAL number(s)

SEROXAT CR Tablet 12.5mg

- MAL06051291ACRZ

SEROXAT CR Tablet 25mg

- MAL06051292ACRZ

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Product Registration Holder

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