

PACKAGE LEAFLET: INFORMATION FOR THE USER

Sertraline KR 50 mg Tablets Sertraline KR 100 mg Tablets

Sertraline Hydrochloride

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Sertraline KR Tablets is and what it is used for
2. Before you take Sertraline KR Tablets
3. How to take Sertraline KR Tablets
4. Possible side effects
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1. WHAT SERTRALINE KR TABLETS IS AND WHAT IT IS USED FOR

How this medicine works

Serotonin is a substance found naturally in the human body. If the amount of serotonin is off balance, this can lead to e.g. symptoms of depression. The active substance in Sertraline tablets, sertraline, inhibits the reuptake of serotonin in nerves and thus corrects the imbalance. Sertraline belongs to a group of antidepressants, which are called SSRI medicines (selective serotonin reuptake inhibitors).

Sertraline tablets are used for the treatment of severe depression.

2. BEFORE YOU TAKE SERTRALINE KR TABLETS

Do not take Sertraline KR Tablets

- If you are allergic (hypersensitive) to sertraline.
- If you have recently had a heart attack.
- If you use medicines, which belong to so-called MAO inhibitors (e.g. antidepressant moclobemide or selegiline which is used to treat Parkinson's disease) or medicines, which contain pimozide (antipsychotic medicine).

Take special care with Sertraline KR Tablets

Discuss with your doctor before you begin using Sertraline KR Tablets if:

- you have to undergo electroconvulsive therapy while you are taking sertraline because there is a lack of experience in these situations.
- you have recently discontinued using some MAO inhibitor. In this case you need to wait at least 14 days before you start using Sertraline tablets unless your doctor has prescribed otherwise.
- you have epilepsy.

- you suffer from a severe heart condition like angina pectoris, heart failure that is not sufficiently controlled or if your heartbeat is severely disturbed (ventricular arrhythmia).
- you have liver disease.

Use in children and adolescents under 18 years of age

Sertraline tablets should normally not be used for children and adolescents under 18 years except for patients over 13 years of age with obsessive-compulsive disorder. Also, you should know that patients under 18 have an increased risk of side-effects such as suicide attempt, suicidal thoughts and hostility (predominantly aggression, oppositional behaviour and anger) when they take this class of medicines. Despite this, your doctor may prescribe Sertraline tablets for patients under 18 because he/she decides that this is in their best interests. If your doctor has prescribed Sertraline tablets for a patient under 18 and you want to discuss this, please go back to your doctor. You should inform your doctor if any of the symptoms listed above develop or worsen when patients under 18 are taking Sertraline tablets. Also, the long-term safety effects concerning growth, maturation and cognitive and behavioural development of Sertraline tablets in this age group have not yet been demonstrated.

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.

Older patients are possibly more sensitive for the effects of sertraline.

Periods of exaggerated cheerfulness together with having lots of energy (mania) or a lighter form (hypo mania) can occur when using sertraline.

The chance of suicide is inextricably bound up with severe depression and this chance can exist after a decrease of the depression. Therefore, your doctor may wish to monitor you closely for signs of suicidal thoughts until your condition improves.

Please ask your doctor if any of the warnings mentioned above applies to you.

Using other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

It is especially important to tell your doctor if you are using some of the following medicines:

- MAO inhibitors (e.g. moclobemide for depression or selegiline for Parkinson's disease) or pimozide (antipsychotic medicine).
- Other antidepressants.
- Medicines that can increase the amount of serotonin in the brain (e.g. tryptophane or fenfluramine).
- Antidiabetics or antidiuretics.

- Diazepam (for the treatment of anxiety, insomnia or drug withdrawal).
- Cimetidine (for the treatment of ulcers and excess acid).
- Warfarin (medicine which prevents blood clotting), acetylsalicylic acid (i.e. Aspirin) or other anti-inflammatory medicines.
- Medicinal products that are metabolised by a certain liver enzyme (CYP 2D6) (e.g. amiodarone and haloperidol).
- Lithium (antipsychotic medicine)
- Pimozide (for the treatment of long term for severe mental illness).

Taking Sertraline tablets with food and drink

This medicine can be taken with or without food.

It is not recommended to consume alcohol during Sertraline treatment.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Pregnancy: There is limited experience of using Sertraline tablets during pregnancy. Therefore, Sertraline tablets should not be used during pregnancy unless clearly prescribed by a doctor. Discuss with your doctor if you are planning to get pregnant or are pregnant.

Breast-feeding: Sertraline passes into breast milk and can affect the infant. Therefore, Sertraline tablets should not be used while breast-feeding unless clearly prescribed by a doctor.

Driving and using machines

Sertraline tablets may cause dizziness, tiredness or affect vision. Therefore, you should avoid driving a car and using machines which require alertness until you know how the medicine affects you.

3. HOW TO TAKE SERTRALINE KR TABLETS

Always take Sertraline KR Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Dosage

Your doctor prescribes a suitable dosage for you. The dosage prescribed by your doctor may vary from 25 mg to 200 mg per day, although 50 mg per day is the most common dosage.

Sertraline tablets are taken once daily either in the morning or in the evening. This medicine can be taken with or without food. The tablets must not be crushed or chewed.

Note!

Improvement will not be noticed immediately, but the effect of Sertraline tablets may occur only after 2-4 weeks treatment.

Treatment of depression is usually continued for 6 months after improvement of condition has occurred. When improvement has occurred, treatment should be continued according to doctor's instructions.

If you take more Sertraline KR Tablets than you should

If you have taken too much medicine, always contact a physician, hospital or poison information centre.

If you forget to take Sertraline KR Tablets

Do not take a double dose to make up for a forgotten dose, but continue using the medicine by taking the next dose at its usual administration time.

If you stop taking Sertraline KR Tablets

Do not stop taking Sertraline KR Tablets without your doctor's order. This medicine is discontinued slowly by gradually decreasing the dose according to the doctor's instructions. If this medicine is stopped too quickly, the following symptoms may occur: dizziness, headache, nausea, restlessness and anxiety. The symptoms are usually mild and disappear automatically.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Sertraline tablets can cause side effects, although not everybody gets them. The side effects usually occur in the beginning of treatment and are alleviated within a few weeks. Sometimes it is difficult to differentiate disease symptoms and side effects.

Very common side effects (occurs in over 1 patient in 10):

Insomnia, dizziness, drowsiness, diarrhoea/loose stools, dry mouth and nausea.

Common side effects (occurs in 1-10 patients in 100):

Eating disorders, agitation, anxiety, headache, reduced sensitivity to touch, overactive muscles, tense muscles, grinding of the teeth, abnormal walking, prickling in the skin, tremors, strange vision, ringing in the ears, palpitations, hot flushes, yawning, stomach pains, constipation, indigestion, vomiting, increased sweating, rashes, disturbances in sexual function (mainly delayed ejaculation in men), chest pain, general weakness and tiredness.

Uncommon side effects (occurs in 1-10 patients in 1000):

Increased appetite, depression, extreme happiness, hallucinations, migraine, fainting, enlarged pupils, rapid heart rate, increased blood pressure, loss of hair, swollen eyes, itching, red spots on the skin, joint pain, muscle cramps, urinary incontinence, swelling, fever, general feeling of ill health and increase or decrease in weight.

Rare side effects (occurs in 1-10 patients in 10000):

Blood disorders, allergic reactions (these can be severe), increased sensitivity, decreased thyroid activity, changes in the production of certain hormones or enzymes, low levels of sodium in the blood, aggression, decreased sexual drive in both men and women, nightmares, mental disorders, coma, seizures, muscle cramps, restlessness and an inability to sit or stand still, agitation, confusion, sweating, diarrhoea, hyperthermia, high blood pressure, stiff muscles, increased heart rate, abnormal bleeding (e.g. nose bleeds, internal bleeding, blood in the urine), breathing difficulties, inflammation of the pancreas, severe liver disorders, swelling and allergic reactions in the skin, swelling of the face, sensitivity to light, severe skin disorders, inability to pass urine, unexpected production of milk from the nipple, development of breasts in males, abnormally long and sometimes painful erections of the penis, abnormal results of laboratory tests, increased cholesterol levels, symptoms associated with drug withdrawal, weakness in the muscles, fainting, worsening of Parkinson's disease, eye disorders, problems with vision, sensitivity to light.

Cases of thoughts/behaviour of harming or killing yourself or have been reported during sertraline therapy or early after treatment has been stopped (see section 2 Take special care with Sertraline KR tablets).

If you experience severe allergic symptoms, contact a doctor immediately.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE SERTRALINE KR TABLETS

Keep out of the reach and sight of children.

Store in the original packaging.

Do not use Sertraline KR Tablets after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Sertraline KR Tablets contains

- The active substance is sertraline (as sertraline hydrochloride). One tablet contains 50 mg or 100 mg of sertraline.
- The other ingredients are calcium hydrogen phosphate, microcrystalline cellulose, sodium starch glycolate, magnesium stearate, hypromellose (E464), titanium dioxide (E171), polydextrose (E1200), glyceryl triacetate and polyethylene glycol.

What Sertraline KR Tablets looks like and contents of the pack

Product description:

50 mg tablets: White to off-white capsule shaped, film-coated tablets with 'ST/50' on one side and 'G' on the other.

100 mg tablets: White to off-white capsule shaped, film-coated tablets with 'ST/100' on one side and 'G' on the other.

Pack sizes:

14, 15, 20, 28, 30, 50, 56, 60, 98, 100, 250, 300 and 500 tablets in a bottle and/or blister package.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

<[To be completed nationally]>

This medicinal product is authorised in the Member States of the EEA under the following names:

Greece: SERTRALINE/Generics
The Netherlands: Sertraline KR Tablets

This leaflet was last approved in {MM/YYYY}.

<[To be completed nationally]>