Zeridame SR 100mg, 150mg, 200mg Prolonged Release tablets

Tramadol hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1 What Zeridame SR is and what it is used for

Zeridame SR is a pain killer. Zeridame SR eases the pain by inhibition of certain chemicals of the central nervous system (in the brain and the spinal cord).

Zeridame SR can be used in adults and adolescents over 12 years of age. It is used for the treatment of moderate to severe pain.
Zeridame SR is not suitable for children under the age of 12 years.

2 What you need to know before you take Zeridame SR

DO NOT take Zeridame SR:
- If you are **allergic** to tramadol hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- If you have **recently drunk too much alcohol or taken too many sleeping tablets, pain killers, opiates** or any medicines that work via the brain (psychotropic medicines).
- When using certain **medicines against depression** (so-called MAO-inhibitors) or when these have been used the last 14 days.
- If you suffer from **epilepsy** that is not controlled by medication.
- For the treatment of withdrawal symptoms in **drug addicts**.

Warnings and precautions

Talk to your doctor or pharmacist before taking Zeridame SR:
- If you have recently had any **head injuries**, or an **increased pressure in the head** (e.g. after an accident)
- If you suffer from disorders of the **kidneys or liver** (see section 3: how to take Zeridame SR)
- If you suffer from **difficulty to breathe**
- If you have a **tendency towards epilepsy or fits** because the risk of a fit may increase. Seizures have been reported in patients taking tramadol at the recommended dose level. The risk may be increased when doses of tramadol exceed the recommended upper daily dose limit (400 mg).
- If you suffer from **addiction to opiates**
- If you suffer from **shock** (cold sweat may be a sign of this)
- If you use **other medicines** or substances that work via the **brain**, including **alcohol**.

After long term treatment (> 3 months) headache may develop or aggravate. When tramadol has been used to treat tension or cluster headache or migraine (which is not a registered use for tramadol) cases have been reported of medication overuse headache (MOH).

Please note that Zeridame SR may lead to physical and psychological addiction. When Zeridame SR is taken for a long time, its effect may decrease, so that higher doses have to be taken (tolerance development). In patients with a tendency to abuse medicines or who are dependent on medicines, treatment with Zeridame SR should only be carried out for short periods and under strict medical supervision.

Tramadol is transformed in the liver by an enzyme. Some people have a variation of this enzyme and this can affect people in different ways. In some people, they may not get enough pain relief but other people are more likely to get serious side effects. If you notice any of the following side effects, you must stop taking this medicine and seek immediate medical advice: slow or shallow breathing, confusion, sleepiness, small pupils, feeling or being sick, constipation, lack of appetite.

Children and adolescents

Use in children with breathing problems
Tramadol is not recommended in children with breathing problems, since the symptoms of tramadol toxicity may be worse in these children.

Other medicines and Zeridame SR

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not take Zeridame SR at the same time, or within 14 days of taking medicines called monoamine oxidase inhibitors (moclobemide or phenelzine for depression, selegiline for Parkinson's disease).

The pain relieving effect of Zeridame SR may be weakened and / or shortened if you also take medicines containing:
- Carbamazepine (used to treat epilepsy)
- Buprenorphine, nalbuphine, or pentazocine (pain killers)
- Ondansetron (used to stop you feeling sick)

The risk of side effects increases:
- if you are taking medicines which may cause convulsions (fits), such as certain antidepressants or antipsychotics. The risk of having a fit may increase if you take Zeridame SR at the same time. Your doctor will tell you whether Zeridame SR is suitable for you.
- if you are taking certain antidepressants. Zeridame SR may interact with these medicines and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C.
- if you take Zeridame SR at the same time as sedative medicines such as tranquillisers, sleeping pills, antidepressants and strong pain relievers (morphine, codeine, pethidine). You may feel excessively drowsy or feel that you might faint.
- if you take Zeridame SR at the same time as blood thinning medicines, such as warfarin. The dose of these medicines may need reducing, otherwise there could be an increased risk of serious bleeding.
- anticonvulsant drugs taken with tramadol can lower the seizure threshold and the risk of convulsions may increase in these patients.

Zeridame SR with alcohol:

Zeridame SR should not be used in combination with alcohol.

Pregnancy and breast-feeding:

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy
Tramadol passes the placenta. There are not enough details known to judge the possible harm in human. Long term treatment during pregnancy may lead to withdrawal symptoms in the newborn after birth, as a consequence of addiction. Therefore tramadol should not be taken during pregnancy. Your doctor will advise you.

Breast-feeding:
Tramadol is excreted into breast milk. For this reason, you should not take Zeridame SR more than once during breast-feeding, or alternatively, if you take Zeridame SR more than once, you should stop breast-feeding.

Driving and using machines:

Zeridame SR can cause drowsiness and dizziness, and blurred vision. Because of this Zeridame SR can affect your ability to drive and operate machinery. This can be intensified by alcohol or by medicine that acts or works via the brain.
Do not drive a car or do other activities that need you to be alert, until you know how tramadol affects you. Please see 4. Possible Side Effects for a full list of possible effects that may impair alertness and coordination.

The medicine can affect your ability to drive as it may make you sleepy or dizzy.
- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
  - The medicine has been prescribed to treat a medical or dental problem and
  - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
  - It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

3 How to take Zeridame SR

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Dose
The dosage should be adjusted to the intensity of your pain and your individual pain sensitivity. In general the lowest pain-relieving dose should be taken. The usual dosage is:

Adults and adolescents over 12 years of age:
The starting dose is:
Zeridame SR 100mg: one tablet (100mg tramadol hydrochloride) twice a day
If this is not sufficient to kill the pain the dose can be increased to:
Zeridame SR 150mg: one tablet (150mg tramadol hydrochloride) twice a day **or**
Zeridame SR 200mg: one tablet (200mg tramadol hydrochloride) twice a day.

If the dose you are prescribed cannot be achieved with this strength tablet, other strengths of this medicinal product are available to achieve the dose.

Elderly patients
In elderly patients (above 75 years) the excretion of tramadol may be delayed. If this applies to you, your doctor may recommend prolonging the dosage interval.

Severe liver or kidney disease (insufficiency) / dialysis patients
Patients with severe liver and / or kidney insufficiency should not take Zeridame SR. If in your case the insufficiency is mild or moderate, your doctor may recommend prolonging the dosage interval.

Method of administration
Zeridame SR is a tablet with a special core to let out the active ingredient slowly and long-lasting in the body. Because of this it can take a bit longer before you notice the effect.
Swallow the tablet whole (without chewing or breaking), with a glass of water.
Preferably administer in the morning and evening. The tablets may be taken on an empty stomach or during the meal.

Duration of the treatment with Zeridame SR
Your doctor will tell you how long you should use Zeridame SR. This depends on the cause of the pain. Do not use Zeridame SR any longer than necessary.

If you notice that Zeridame SR is too strong or is not strong enough, talk to your doctor or pharmacist.

If you take more Zeridame SR than you should:

If you have taken too many Zeridame SR you should immediately contact your doctor, nearest hospital or clinic. The possible symptoms that may occur are: pin-point pupils, vomiting, a fall in blood pressure, a fast heartbeat, collapse, disturbed consciousness including coma (deep unconsciousness), epileptic fits and difficulties in breathing.

If you forget to take Zeridame SR:

If you forgot to take the tablets, pain is likely to return. Do not take a double dose to make up for forgotten individual doses, simply continue taking tablets as before.

If you stop taking Zeridame SR:

If you interrupt or finish treatment with Zeridame SR too soon, pain is likely to return. You should not suddenly stop taking this medicine unless your doctor tells you to. If you want to stop taking your medicine, discuss this with your doctor first, particularly if you have been taking it for a long time. Your doctor will advise you when and how to stop, which may be by lowering the dose gradually to reduce the chance of developing unnecessary side effects (withdrawal symptoms).
Generally there will be no after effects when treatment with Zeridame SR is stopped. However, on rare occasions, people who have been taking Zeridame SR tablets for some time may feel unwell if they abruptly stop taking them. They may feel agitated, anxious, nervous or shaky. They may be hyperactive, have difficulty sleeping and have stomach or bowel disorders. Very few people may get panic attacks, hallucinations, unusual perceptions such as itching, tingling and numbness, and noise in the ears (tinnitus). If you experience any of these complaints after stopping Zeridame SR, please consult your doctor.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, Zeridame SR tablets can cause side effects, although not everybody gets them.
The following side effects can occur:

Very common (may affect more than 1 in 10 people): nausea and dizziness.

Common (may affect up to 1 in 10 people): headache, confusion, vomiting, constipation, dry mouth, sweating, drowsiness, fatigue.

Uncommon (may affect up to 1 in 100 people): heart palpitations, irregular heart beat, low blood pressure - especially when standing up, heart failure (cardiovascular collapse), uneasiness (qualm), pressure on the stomach, feeling of fullness, itch, rash and rash with severe itch and forming of lumps (hives or urticaria), diarrhoea.

Rare (may affect up to 1 in 1,000 people): blurred vision, slower heartbeat than normal, increase in blood pressure, changes in appetite, itch or tingling without cause, shaking, breathing slower than normal, convulsions, hallucinations, confusion, sleep disturbances and nightmares, allergic reactions (e.g. shortness of breath), tightness of the chest by cramp of the muscles of the airways (bronchospasm), gasping, sudden fluid accumulation in the skin and mucosa (e.g. throat or tongue), breathing problems (respiration difficulties) and / or itch and hypersensitiveness. Also reported: mood changes, changes in activity, changes in the observation or the ability to make decisions, muscle weakness, difficulties passing water, involuntary muscle contractions, abnormal coordination, and fainting (syncope).

Not known (frequency cannot be estimated from the available data): enlarged pupils. Decrease in blood sugar level.

Side effects that occur at withdrawal, identical to withdrawal symptoms with opiates, can be: agitation, anxiety, fear, nervousness, sleeplessness, difficulty keeping still (hyperkinesias), shaking (tremor) and stomach discomfort (gastro-intestinal disorders).

Allergic reaction (e.g difficulty in breathing, wheezing, swelling of skin), shock (sudden circulation failure) and increase in liver enzyme values have occurred in very rare cases (affects less than 1 user in 10,000). **You should see a doctor immediately if you experience symptoms such as swollen face, tongue and / or throat and / or difficulty to swallow or hives together with difficulties in breathing.**

Reporting of side effects

If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra. gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Zeridame SR

- Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and / or bottle and the carton after "exp". The expiry date refers to the last day of that month.

- Store in the original package in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What Zeridame SR contains:

The active substance is: tramadol hydrochloride
- 1 tablet of Zeridame SR 100mg, contains 100mg tramadol hydrochloride.
- 1 tablet of Zeridame SR 150mg, contains 150mg tramadol hydrochloride.
- 1 tablet of Zeridame SR 200mg, contains 200mg tramadol hydrochloride.

The other ingredients are: calcium hydrogen phosphate (E341), hydroxypropyl cellulose (E463), colloidal anhydrous silica (E551), and magnesium stearate (E470b).

What Zeridame SR looks like and contents of the pack:

Zeridame SR 100mg Prolonged Release Tablets are off white, round biconvex tablets.
Zeridame SR 150mg Prolonged Release Tablets are off white, capsule shaped tablets.
Zeridame SR 200mg Prolonged Release Tablets are off white, capsule shaped tablets.

Zeridame SR 100mg; 150mg; 200mg: packs of -10, 20, 30, 50, 60, 90, 100, 120, 180 or 500 white tablets in blisters or in plastic tablet containers.
Not all pack sizes may be marketed.

Marketing Authorisation Holder:
Actavis Group PTC ehf.
Reykjavíkurvegi 76-78,
220 Hafnarfjörður, Iceland

Manufacturer:
Medochemie Ltd
Facility A – Z, Mich. Erakleous, Ayios Athanassios Industrial Area, Limassol, Cyprus.

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