Zamadol® SR 50 mg prolonged-release hard capsules

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17.04.23[11]

(tramadol hydrochloride)

PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start taking this medicine, because it contains important information for you.
- 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.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If you get any of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See Section 4.

Your medicine is available using the above name but will be referred to as Zamadol SR prolonged-release hard capsules throughout the following leaflet. This medicine is also available in other strengths of 100 mg, 150 mg and 200 mg.

What is in this leaflet:

1. WHAT ZAMADOL SR PROLONGED-RELEASE HARD CAPSULES IS AND WHAT IT IS USED FOR

Zamadol SR prolonged-release hard capsules belongs to a group of medicines called analgesics, commonly known as pain killers or pain relievers. The active substance, tramadol hydrochloride, interrupts the pain messages being sent to your brain, and it also acts in your brain to stop pain messages from being felt. This means that Zamadol SR prolonged-release hard capsules does not stop the pain from happening, but you will not be able to feel the pain as much.

Zamadol SR prolonged-release hard capsules is used to relieve moderate to severe pain (for example, pain after an operation, or after an injury).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ZAMADOL SR PROLONGED-RELEASE HARD CAPSULES

Do not take Zamadol SR prolonged-release hard capsules:
- if you are allergic to tramadol hydrochloride or to any of the other ingredients of this medicine (listed in Section 6) resulting in a skin rash, swelling of face or difficulty in breathing
- if you are taking, or you have taken in the last two weeks, monoamine oxidase inhibitors (MAOIs) to treat your depression (see Section 2, "Other medicines and Zamadol SR prolonged-release hard capsules")
- if you have epilepsy which is not controlled by treatment
- if you have drunk enough alcohol to make you feel woozy or drunk
- if you have taken more than the prescribed dose of your sleeping tablets, antipsychotics, antidepressants (antipsychotics and antidepressants are medicines that affect mood and emotions) or other pain killers, which can slow down your breathing and reactions.

Warnings and precautions

Talk to your doctor or pharmacist before taking Zamadol SR prolonged-release hard capsules, if:
- you have had an allergic reaction to any morphine-like medicines.
- you have been taking Zamadol SR prolonged-release hard capsules or any other tramadol containing medicine for a long time.
- you are addicted to morphine.
- you have severe problems with your liver or kidneys.
- you have recently had a head injury or have a very bad headache that makes you sick.
- you have ever had convulsions (fits) or do you suffer from epilepsy.
- you have asthma or trouble breathing.
- you are going to have surgery requiring a general anaesthetic.
- you suffer from depression and you are taking antidepressants as some of them may interact with tramadol (see 'Other medicines and Zamadol SR prolonged-release hard capsules').

Sleep-related breathing disorders

Zamadol SR prolonged-release hard capsules can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

Talk to your doctor if you experience any of the following symptoms while taking Zamadol SR prolonged-release hard capsules:
Extreme fatigue, lack of appetite, severe abdominal pain, nausea, vomiting or low blood pressure. This may indicate that you have adrenal insufficiency (low cortisol levels). If you have these symptoms, contact your doctor, who will decide if you need to take hormone supplement.

There is rare possibility that Zamadol SR prolonged-release hard capsules may cause convulsions (fits). The risk is increased if doses above the daily maximum are taken and if you are also taking anti-depressants or antipsychotics.

If you have a tendency to drug addiction or abuse you should take Zamadol SR prolonged-release hard capsules for short periods only. Please tell your doctor about this as your doctor may want to monitor your pain control more closely.

You should not take this product for the treatment of withdrawal symptoms, if you are addicted to drugs.

There is a small risk that you may experience a so-called serotonin syndrome that can occur after having taken tramadol in combination with certain antidepressants or tramadol alone. Seek medical advice immediately if you have any of the symptoms related to this serious syndrome (see section 4 'Possible side effects').

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:

Zamadol SR prolonged-release hard capsules prolonged-release capsules, hard should not be used in children under 12 years of age.

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 Zamadol SR prolonged-release hard capsules

Tell your doctor or pharmacist or dentist if you are taking, have recently taken or might take any other medicines, including those obtained without prescription.

Do not take Zamadol SR prolonged-release hard capsules 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 Zamadol SR prolonged-release hard capsules may be weakened and/or shortened if you also take medicines containing:
- carbamazepine (used to treat epilepsy)
- buprenorphine, nalbuphine, or pentazocine (pain killers)
- ondansetron (prevents nausea)

Your doctor will tell you whether you should take Zamadol SR prolonged-release hard capsules and what dose.

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 Zamadol SR prolonged-release hard capsules at the same time. Your doctor will tell you whether Zamadol SR prolonged-release hard capsules are suitable for you.

The risk of side effect increases, if you are taking certain antidepressants. Zamadol SR prolonged-release hard capsules may interact with these medicines and you may experience serotonin syndrome (see section 4 'Possible side effects').

Medicines that act on the nervous system such as hypnotics, tranquillisers, sleeping pills and pain killers may make you feel drowsier or faint when taken with Zamadol SR prolonged-release hard capsules.

Anticoagulants to thin your blood such as warfarin. The effectiveness of the medicines may be altered if you are also taking Zamadol SR prolonged-release hard capsules.

You must tell your doctor if you are taking these medicines.

Concomitant use of Zamadol SR prolonged-release hard capsules and sedative medicines such as benzodiazepines or related drugs increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However if your doctor does prescribe Zamadol SR prolonged-release hard capsules together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all sedative medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Zamadol SR prolonged-release hard capsules with food, drink and alcohol

Zamadol SR prolonged-release hard capsules should be taken with some water, with or without the meal. Avoid drinking alcohol while taking this medicine.

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. Please contact your doctor if you become pregnant during your treatment.

Pregnancy

Zamadol SR prolonged-release hard capsules should not be taken during pregnancy or while breast-feeding. This is because it is not yet known how safe it is to take this medicine when you are pregnant. Contact your doctor if you become pregnant during your treatment.

Breast-feeding

Tramadol is excreted into breast milk. For this reason, you should not take Zamadol SR prolonged-release hard capsules more than once during breast-feeding, or alternatively, if you take Zamadol SR prolonged-release hard capsules more than once, you should stop breast-feeding.

Driving and using machines

Zamadol SR prolonged-release hard capsules may cause drowsiness and this effect may be potentiated by alcohol, antihistamines and other CNS depressants. If patients are affected they should be warned not to drive or operate machinery unless they know how Zamadol SR prolonged-release hard capsules affects them.
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.

Zamadol SR prolonged-release hard capsules contains sucrose.

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE ZAMADOL SR PROLONGED-RELEASE HARD CAPSULES

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

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.

Swallow the capsules whole with water without chewing.

If you have difficulty in swallowing, you may open the capsules. You must open them very carefully by pulling and twisting each end over a spoon so that all the pellets stay in the spoon. Do not chew. Swallow all the pellets with water.

Dosage for adults and adolescents from 12 years of age:
The usual initial dose is 50-100 mg twice daily, in the morning and in the evening. Your doctor may increase this dose up to 150-200 mg twice daily according to your needs. You should normally take your Zamadol SR prolonged-release hard capsules every 12 hours, at the same time each morning and evening.

The maximum dose is usually 400 mg daily.

Use in children:
Zamadol SR prolonged-release hard capsules should not be taken by children under 12 years of age.

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

Use in patients with severe liver or kidney disease (insufficiency) dialysis patients:

Patients with severe liver and/or kidney insufficiency should not take Zamadol SR prolonged-release hard capsules. If in your case the problem is mild or moderate your doctor may recommend prolonging the dosage interval.

If you take more Zamadol SR prolonged-release hard capsules than you should
If you accidentally take more capsules than your prescribed dose, tell your doctor or pharmacist immediately and if necessary contact your nearest hospital casualty department. Remember to take the pack and any remaining medicines with you.

If you forget to take Zamadol SR prolonged-release hard capsules
Do not take a double dose to make up for a forgotten dose.

If you stop taking Zamadol SR prolonged-release hard capsules
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).

People who have been taking Zamadol SR prolonged-release hard capsules 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. If you experience any of these complaints after stopping Zamadol SR prolonged-release hard capsules, 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, Zamadol SR prolonged-release hard capsules can cause side effects, although not everybody gets them.

The most serious side effects which may occur include allergic reaction (difficulty in breathing, wheezing and swelling of the face or throat), anaphylactic reaction (an extreme allergic reaction resulting in difficulty breathing, changes in heart rate, faintness, collapse or unconsciousness due to a drop in blood pressure) or convulsions (fits). If you have any of these symptoms you must stop taking Zamadol SR prolonged-release hard capsules immediately and seek medical advice.

Very Common (may affect more than 1 in 10 people)
- Dizziness
- Vomiting and nausea (being and feeling sick)

Common (may affect up to 1 in 10 people)
- Headache
- Drowsiness, sleepiness (fatigue)
- Constipation, dry mouth
- Sweating

Uncommon (may affect up to 1 in 100 people)
- Rapid heart beat, palpitation, sudden drops in blood pressure. These adverse effects may occur especially on intravenous administration and in patients who are physically stressed
- Itching, skin rash
- Retching, feeling bloated or full

Rare (may affect up to 1 in 1000 people)
- Appetite changes
- Psychic effects including: changes in mood, activity, behaviour and perception, hallucinations, confusion, restlessness, sleep disturbances and nightmares
- Convulsions (fits)
- Tingling sensation and trembling
- Slow heart-beat, increase in blood pressure
- Muscle weakness
- Difficulty or inability in passing urine
- Blurred vision

Very rare (may affect up to 1 in 10,000 people)
- Flushing
- Vertigo (feeling of dizziness or “spinning”)
- Asthma and breathing difficulties
- Elevated liver enzymes

Not known: frequency cannot be estimated from the available data
- Decrease in blood sugar level
- Low blood levels of sodium which can cause tiredness and confusion, muscle twitching, fits and coma
- Hiccups
- Serotonin syndrome, that can manifest as mental status changes (e.g. agitation, hallucinations, coma), and other effects, such as fever, increase in heart rate, unstable blood pressure, involuntary twitching, muscular rigidity, lack of coordination and/or gastrointestinal symptoms (e.g. nausea, vomiting, diarrhoea) (see section 2 ‘What you need to know before you take Zamadol SR prolonged-release hard capsules’).

Withdrawal symptoms including: agitation, anxiety, nervousness, difficulty sleeping, restlessness, trembling and gastro-intestinal problems (see Section 3, “How to take Zamadol SR prolonged-release hard capsules”).

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via 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 ZAMADOL SR PROLONGED-RELEASE HARD CAPSULES
- Do not store above 25°C.
- Store in the original package in order to protect from moisture.
- Keep out of the sight and reach of children.
- Do not use Zamadol SR prolonged-release hard capsules after the expiry date which is stated on the carton. 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.
- If your capsules become discoloured or show any other signs of deterioration please ask your doctor or pharmacist before taking your medicine.

6. CONTENT OF THE PACK AND OTHER INFORMATION
What Zamadol SR prolonged-release hard capsules contains:
The active substance is tramadol hydrochloride.
Each prolonged-release capsule contains 50 mg tramadol hydrochloride.
The other ingredients of the capsule contents are: sugar spheres (sucrose and maize starch), colloidal anhydrous silica, ethylcellulose, shellac, talc.
The capsule contains:
Gelatin, titanium dioxide (E171), iron oxide yellow (E172), indigotine (E132).

The printing ink contains:
Shellac, iron oxide black (E172), propylene glycol, ammonium hydroxide.

What Zamadol SR prolonged-release hard capsules look like and the contents of the pack:
Zamadol SR prolonged-release hard capsules are dark green and marked with T50SR in black ink.

This medicinal product is in the form of a prolonged release hard capsule. The capsules release the active ingredient over a period of time.

All the capsules are packaged in PVC/PVDC-aluminium blisters of 10 capsules. Each pack contains 6 blisters, i.e. each pack contains 60 capsules per pack.

MANUFACTURER AND PRODUCT LICENCE HOLDER
Manufactured by Temmler Pharma GmbH, Marburg, Germany.
Procured from within the EU by product licence holder Star Pharmaceuticals Ltd, 5 Sandridge Close, Harrow, Middlesex, HA1 1XD. Repackaged by Servipharm Ltd.

POM | CD | PL 20636/2627

Leaflet revision and issue date (Ref) 17.04.23[11]

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