

Zamadol® SR 100 mg prolonged-release hard capsules

(tramadol hydrochloride)

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PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start taking 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 get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Your medicine is available using the above name but will be referred to as Zamadol SR prolonged-release hard capsules throughout the following leaflet.

Zamadol SR prolonged-release hard capsules are also available in other strengths of 50 mg, 150 mg and 200 mg.

In this leaflet:

1. What Zamadol SR prolonged-release hard capsules is and what it is used for
2. Before you take Zamadol SR prolonged-release hard capsules
3. How to take Zamadol SR prolonged-release hard capsules
4. Possible side effects
5. How to store Zamadol SR prolonged-release hard capsules
6. Further information

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. BEFORE YOU TAKE ZAMADOL SR PROLONGED-RELEASE HARD CAPSULES

Do not take Zamadol SR prolonged-release hard capsules:

- if you are allergic (hypersensitive) to tramadol hydrochloride or to any of the other ingredients resulting in a skin rash, swelling of face or difficulty in breathing (see section 6, “Further Information”)
- if you are taking, or you have taken in the last two weeks, monoamine oxidase inhibitors (MAOIs) to treat your depression (see section 2, “Taking other medicines”)
- 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, antidepressant (antipsychotics and antidepressants are medicines that affect mood and emotions) or other pain killers, which can slow down your breathing and reactions.

Take special care with Zamadol SR prolonged-release hard capsules

- If taken for long periods there is the rare possibility that addiction may develop.
- There is the 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 antidepressants 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 he/she may want to monitor your pain control more closely.
- You should not take this product for the treatment of withdrawal symptoms in drug addicts.

Before taking Zamadol SR prolonged-release hard capsules you must tell your doctor:

- if you are pregnant or breast feeding.
 - if you have been taking Zamadol SR prolonged-release hard capsules or any other tramadol containing medicine for a long time.
 - if you are addicted to morphine.
 - if you have had an allergic reaction to any morphine-like medicines.
 - if you have severe problems with your liver or kidneys.
 - if you have recently had a head injury or have a very bad headache that makes you sick.
 - if you have ever had convulsions (fits) or you suffer from epilepsy.
 - if you have asthma or trouble breathing.
 - if you are taking other medicines.
 - if you are going to have surgery requiring a general anaesthetic.
- If any of the above apply to you, you must tell your doctor as he/she may decide to alter your treatment.

Taking other medicines

Please **tell your doctor or pharmacist** if you are taking or have recently taken 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 certain antidepressants. Zamadol SR prolonged-release capsules 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. **You must tell your doctor** if you are taking these medicines.
- 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 capsules are suitable for you.

- 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.
- Tell your doctor or dentist if you are taking any of these medicines.

Taking Zamadol SR prolonged-release hard capsules with food and drink

You can take Zamadol SR prolonged-release hard capsules with or without a meal. Avoid drinking alcohol while taking this medicine.

Pregnancy and breast-feeding

Zamadol SR prolonged-release hard capsules should not be taken during pregnancy or while breastfeeding. This is because it is not yet known how safe it is to take this medicine when you are pregnant.

Ask your doctor or pharmacist for advice before taking any medicine. Please contact your doctor if you become pregnant during your treatment.

Driving and using machines

Zamadol SR prolonged-release hard capsules may cause drowsiness, particularly if taken with alcohol, anti-histamines and other medicines that may cause drowsiness.

Do not drive or operate heavy machinery unless you know how Zamadol SR prolonged-release hard capsules affects you.

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.

Important information about some of the ingredients of Zamadol SR prolonged-release hard capsules

This medicine 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

Dosage for adults:

Always take Zamadol SR prolonged-release hard capsules exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual initial dose is 50 – 100 mg twice daily, morning and 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 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 **maximum dose** is usually 400 mg daily.

Dosage for children and adolescents:

Over 12 years – as for adults (see above).

Under 12 years – **Zamadol SR prolonged-release hard capsules should not be taken by children under 12.**

Dosage for 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 Zamadol SR prolonged-release hard capsules. If in your case the problem is mild or moderate your doctor may recommend prolonging the dosage interval.

Ask your doctor or pharmacist if:

- you are not sure how many capsules to take or when to take them

Tell your doctor or pharmacist if

- you think that the effect is too strong or too weak

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.

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

Do not stop taking Zamadol SR prolonged-release hard capsules, or lower the dose, without first checking with your doctor. Generally there will be no after-effects when treatment with Zamadol SR prolonged-release hard capsules is stopped. However, on rare occasions, 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 further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all other 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 (occurs in more than 1 in 10 patients)

- Dizziness
- Vomiting and nausea (being and feeling sick)

Common (occurs in more than 1 in 100 patients and less than 1 in 10 patients)

- headache
- drowsiness, sleepiness (fatigue)
- constipation, dry mouth
- sweating

Uncommon (occurs in more than 1 in 1,000 patients and less than 1 in 100 patients)

- 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 (occurs in more than 1 in 10,000 patients and less than 1 in 1000 patients)

- allergic reaction such as difficulty in breathing, wheezing, swelling of the face or throat.
- anaphylactic reaction (an extreme allergic reaction)
- 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 (occurs in less than 1 in 10,000 patients including isolated cases)

- flushing
- vertigo (feeling of dizziness or “spinning”)
- asthma and breathing difficulties
- elevated liver enzymes

Frequency not known (cannot be estimated from the available data)

- low blood sugar level

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, 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.

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. FURTHER INFORMATION

What Zamadol SR prolonged-release hard capsules contains:

The active substance is tramadol hydrochloride.

Each prolonged-release capsule contains 100 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 (E 171).

The printing ink contains:

Shellac, iron oxide black (E 172), 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 white and marked with T100SR 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 and Co. KG, 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.

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

Austria	Adamon SR 50/100/150/200 mg-Kapseln
Belgium	Tradonal Retard 50/100/150/200 mg, gélules à libération prolongée Tradonal Retard 50/100/150/200 mg, capsules met verlengde afgifte, hard Tradonal Retard 50/100/150/200 mg, Hartkapseln, retardiert
Denmark	Gemadol Retard
France	Zamudol LP 50/100/150/200 mg, gélule à libération prolongée
Germany	Travex retard 50/100/150/200 mg Hartkapseln, retardiert
Italy	Tradonal SR 50/100/150/200 mg 30/60 capsula rigide rilascio prolungato
Luxembourg	Tradonal Retard 50/100/150/200 mg, gélules à libération prolongée Tradonal Retard 50/100/150/200 mg, capsules met verlengde afgifte, hard Tradonal Retard 50/100/150/200 mg, Hartkapseln, retardiert
The Netherlands	Tramadol Retard 50/100/150/200 mg
Portugal	Travex Cápsula dura de libertação prolongada
Spain	Tradonal retard x mg cápsulas duras de liberación prolongada
Sweden	Gemadol 50/100/150/200 mg depotkapsel hård
United Kingdom	Zamadol SR 50/100/150/200 mg prolonged-release hard capsules

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