PACKAGE LEAFLET: INFORMATION FOR THE USER

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Larapam 100 mg, 150 mg, 200 mg SR Tablets

Tramadol 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.

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In this leaflet:

1 What Larapam SR Tablets are and what they are used for

Tramadol, the active substance in Larapam SR Tablets, is a painkiller (analgesic) of the opioid group. Its pain alleviating effect is due to its influence on specific nerve cells in the spinal cord and in the brain.

Larapam SR Tablets are used in the treatment of moderate to severe pain.

2 Before you take Larapam SR Tablets

Do not take Larapam SR Tablets:
- if you are allergic (hypersensitive) to tramadol or any of the other ingredients of this medicine
- if you have acute intoxication with alcohol, sleeping agents, painkillers, opioids or other psychotropic agents (medicines which influence mood, emotional status and disposition)
- if you are taking, or have taken in the last two weeks, certain medicines called “monoamine oxidase inhibitors” or MAOIs (used to treat depression). (see “Taking other medicines”)
- if you have epilepsy that is not controlled with your current medicine
- as a drug substitute for the treatment of drug addiction

Take special care with Larapam SR Tablets if you:
- think you may already be dependent on other opioid painkillers
- react sensitively to opiates
- have a consciousness disturbance or are in shock (cold sweat can be an indication of this)
- have difficulty in breathing
- have a head injury or brain diseases that may cause elevated pressure in the skull
- have a liver or kidney disorder
- suffer from epilepsy or seizures (fits) or have had them in the past.
- have or ever had a blood level low in sodium

If any of the above applies to you, please talk to your doctor before starting to take this medicine.

Please note that psychological and physical dependence can develop in patients on Larapam SR Tablets. During long-term use, the effects of this medicine may weaken, with the result that it becomes necessary to use a higher dose (development of tolerance). For this reason, Larapam SR Tablets must be used for short periods only and under strict medical supervision in patients at risk of developing drug dependence.

Please also inform your doctor if any of these problems develops while you are taking this medicine and if you have experienced such problems in the past.

Taking 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.

Do not take Larapam SR Tablets at the same time as medicines called “monoamine oxidase inhibitors” (which are used to treat depression), or if you have taken one in the past 2 weeks. The combination could result in a serious, potentially life threatening interaction.

The pain-relieving effect of Larapam SR Tablets may be weakened and/or shortened if you also take medicines containing:
- carbamazepine (used to treat epilepsy)
- pentazocine, nalbuphine or buprenorphine (painkillers)
- ondansetron (used to reduce vomiting)

The risk of side effects is greater if you take Larapam SR Tablets at the same time as:
- sedative medicines such as tranquillizers, sleeping pills, antidepressants and other pain relievers (morphine, codeine). You may feel excessively drowsy or feel that you might faint.
- tricyclic and SSRI antidepressants. There may be an increased risk of epileptic fits and in isolated cases “serotonin syndrome” may develop, the symptoms of which include confusion, restlessness, diarrhoea, fever and sweating.
- medicines that inhibit blood clotting, such as warfarin. The dose of these medicines may need to be reduced, otherwise there could be an increased risk of potentially serious bleeding.

Taking Larapam SR Tablets with food and drink
Do not drink alcohol while taking Larapam SR Tablets; this could enhance the effects of the medicine.

Pregnancy and breast-feeding
Ask your doctor or pharmacist for advice before taking any medicine.

Pregnancy: There is very little information regarding the safety of tramadol in human pregnancy, therefore this medicine should not be used in pregnant women.

Breast-feeding: Very small quantities of tramadol are excreted into breast milk. As a rule, it is not necessary to interrupt breast-feeding after taking a single dose of tramadol. If repeated administration is necessary you should suspend breast-feeding. If you have to take tramadol for several days, i.e. for more than 2 to 3 days, you must not breast-feed.

Driving and using machines
This medicine may cause side effects such as drowsiness and blurred vision. If this happens, do not drive or use any tools or machines and do not perform any hazardous tasks.

3 How to take Larapam SR Tablets

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

- Swallow the tablets whole with a glass of water.
- Do not break or chew the tablets.
- The tablets can be taken with or without food.

The usual doses are given below. Your doctor may gradually increase or decrease your dose depending on how you respond to the treatment.
It is important that you do not continue to take this medicine for longer than absolutely necessary.

Adults and adolescents aged 12 years and over:
- The usual initial dose is 100 mg twice daily.
- Take one tablet in the morning and one in the evening.

There must be a minimum interval of 8 hours between each dose.
As a general rule, you should take no more than the minimum dose you require to control your pain. You should not take a dose of more than 400 mg of the active substance daily unless there are specific medical reasons for this.

Children under 12 years:
This medicine is not recommended in children under 12 years.

Elderly patients:
- The usual adult dose may be used in elderly patients, although doses may need to be given less frequently especially in patients above the age of 75 years.

Patients with liver or kidney problems/dialysis patients:
If you suffer from severe liver or kidney problems, you should not use this medicine. In less severe cases, your doctor may increase the length of time between each dose of medicine.

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If you take more Larapam SR Tablets than you should
If you take one prolonged release tablet more than prescribed by mistake this will not normally have any negative consequences for you. Continue to take Larapam SR Tablets as your pain recurs as usual.
If you have taken an excessive dose of the medicine the following signs can occur: pin-point pupils, vomiting (being sick), a fall in blood pressure, rapid heartbeat, collapse, disturbed consciousness including coma, epileptic fits and difficulties in breathing. If you observe any of these symptoms or if a child accidentally takes this medicine, immediately contact the nearest doctor or hospital for help!

If you forget to take Larapam SR Tablets
you may experience recurrence of pain. Do not take a double dose to make up for a forgotten dose, but continue to take the preparation as prescribed.

If you stop taking Larapam SR Tablets
If you interrupt or prematurely stop treatment with Larapam SR Tablets, your pain will return. If you decide you wish to stop taking this preparation because of unpleasant side effects, please consult your doctor.

There will normally be no after-effects when you stop taking Larapam SR Tablets. However, in a few cases in which patients have been taking Larapam SR Tablets for a very long period, there have been after-effects such as restlessness, anxiety, nervousness, insomnia, tremor or gastrointestinal upset. If you experience any of these side effects when you stop taking Larapam SR Tablets, please consult your doctor.

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

4 Possible side effects

Like all medicines, Larapam SR Tablets can cause side effects, although not everybody gets them.

Serious side effects
This medicine can occasionally cause allergic reactions although serious allergic reactions are rare (affects 1 to 10 users in 10,000). Stop taking this medicine and tell your doctor *straight away* if you experience any of the following symptoms of a serious allergic reaction:
- sudden wheezing, difficulty in breathing or dizziness
- swelling of the face or throat

Other possible side effects
Tell your doctor if any of the following side effects bothers you:

Very common (affects more than 1 user in 10):
- feeling or being sick (nausea, vomiting)
- dizziness

Common (affects 1 to 10 users in 100):
- headache
- drowsiness, fatigue
- constipation, dry mouth
- sweating
- vomiting

Uncommon (affects 1 to 10 users in 1,000):
- faster, stronger or irregular heartbeat
- collapse or a fall in blood pressure on standing up, which causes dizziness, light-headedness or fainting
- retching, a feeling of pressure in the stomach, stomach bloating
- pruritus, rash, and raised, red, itchy skin rash (hives)
- diarrhoea

Rare (affects 1 to 10 users in 10,000 people):
- slower heartbeat
- rise in blood pressure
- changes in appetite
- tingling or numbness in the hands and feet
- tremor
- epileptic-like seizures
- difficulty sleeping, nightmares
- mood changes
- changes in activity (usually reduced, sometimes increased)
- changes in sensory perception and impairment of the ability to recognize, which can lead to inappropriate decisions
- hallucinations, confusion
- breathing difficulties, worsening of asthma
- blurred vision
- reduced muscle strength
- difficulty in passing urine, producing less urine than normal
- drug dependence (addiction), withdrawal symptoms may occur when treatment is stopped (see "If you stop taking Larapam SR Tablets")
- involuntary muscle contractions
- lack of coordination
- loss of conciousness
- anxiety
- difficulty and pain when passing urine.

Very rare (affects less than 1 user in 10,000):
- sudden onset of skin redness
- a feeling of dizziness or “spinning”
- blood tests which show changes in the way the liver is working

not known (frequency cannot be estimated from the avilable data):
- blood level low in sodium

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 Larapam SR Tablets

Keep Larapam SR Tablets out of reach and sight of children.

Do not use Larapam SR Tablets after the expiry date which is stated on the package after " Do not use after:" or “EXP.:” The expiry date refers to the last day of that month.
Do not store Larapam SR Tablets above 25°C.

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 Larapam SR Tablets contains
The active substance is tramadol hydrochloride. Each Larapam SR tablet contains 100, 150 or 200 mg tramadol hydrochloride.

The other ingredients are: calcium hydrogen phosphate dihydrate (E341), colloidal anhydrous silica (E551), hyprolose (E463), magnesium stearate (E470B).

What Larapam SR Tablets looks like and contents of the pack
Larapam SR Tablets 100, prolonged-release tablet: the tablets are off white and round.

Larapam SR Tablets 150, prolonged-release tablet: the tablets are off white and capsule-shaped.

Larapam SR Tablets 200, prolonged-release tablet: the tablets are off white and capsule-shaped.

The contents of the packages are 10, 20, 30, 50, 60, 100 and 100x1 (unit dose) tablets in PVC/Aluminium blisters.

Not all package sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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