

Package leaflet: Information for the patient

Larapam 100 mg, 150 mg, 200 mg SR 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 Larapam SR Tablets are and what they are used for
2. What you need to know before you take Larapam SR Tablets
3. How to take Larapam SR Tablets
4. Possible side effects
5. How to store Larapam SR Tablets
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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. What you need to know before you take Larapam SR Tablets

Do not take Larapam SR Tablets:

- if you are allergic to tramadol or any of the other ingredients of this medicine (listed in section 6)
- in acute poisoning with alcohol, sleeping agents, centrally acting painkillers, opioids or other psychotropic medicines (medicines which influence mood, emotional status and disposition).
- if you are also taking certain medicines called “monoamine oxidase inhibitors” or MAOIs (used to treat depression or Parkinson’s disease) or have taken them in the last 14 days before treatment with Larapam SR Tablets (see “Other medicines and Larapam SR Tablets”)
- if you have epilepsy and your fits are not adequately controlled by treatment
- as a drug substitute in drug withdrawal treatment

Warnings and precautions

Talk to your doctor before taking Larapam SR Tablets if you:

- think you may already be dependent on other opioid painkillers

- react sensitively to opiates
- have a consciousness disturbance (if you feel that you are going to faint)
- are in shock (cold sweat can be an indication of this)
- have difficulty in breathing
- suffer from increased pressure in the brain (possibly after a head injury or brain disease)
- have a liver or kidney disorder
- suffer from epilepsy or seizures (fits) or have had them in the past.
- suffer from depression and you are taking antidepressants as some of them may interact with tramadol (see “Other medicines and Larapam SR”).

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”).

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

Sleep-related breathing disorders: Larapam SR 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.

Epileptic fits have been reported in patients taking tramadol at the recommended dose level. The risk may be increased if the recommended upper daily dose limit of 400 mg tramadol hydrochloride is exceeded or if you are taking medicines concomitantly which lower the seizure threshold (see “Other medicines and Larapam SR Tablets”).

Tolerance, dependence, and addiction

This medicine contains tramadol which is an opioid medicine. Repeated use of opioids can result in the drug being less effective (you become accustomed to it, known as tolerance). Repeated use of **Larapam SRLarapam SR** can also lead to dependence, abuse and addiction, which may result in life-threatening overdose. The risk of these side effects can increase with a higher dose and longer duration of use.

Dependence or addiction can make you feel that you are no longer in control of how much medicine you need to take or how often you need to take it.

The risk of becoming dependent or addicted varies from person to person. You may have a greater risk of becoming dependent on or addicted to **Larapam SRLarapam SR** if:

- You or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs (“addiction”).
- You are a smoker.
- You have ever had problems with your mood (depression, anxiety, or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

If you notice any of the following signs whilst taking **Larapam SRLarapam SR**, it could be a sign that you have become dependent or addicted:

- You need to take the medicine for longer than advised by your doctor
- You need to take more than the recommended dose
- You are using the medicine for reasons other than prescribed, for instance, ‘to stay calm’ or ‘help you sleep’
- You have made repeated, unsuccessful attempts to quit or control the use of the medicine
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again (‘withdrawal effects’)

If you notice any of these signs, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to stop safely (See section 3, If you stop taking Larapam SRLarapam SR).

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.

Talk to your doctor if you experience any of the following symptoms while taking Larapam SRLarapam SR:

- 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.

Children and adolescents

Larapam SR Tablets are not suitable for use in children of less than 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.

Elderly

Patients of more than 75 years of age should be monitored carefully as the elimination of tramadol can be prolonged (see section 3 “How to take Larapam SR Tablets”).

Other medicines and Larapam SR Tablets

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

Do not take Larapam SR Tablets at the same time as medicines called “monoamine oxidase inhibitors” or MAOIs (which are used to treat depression or Parkinson’s disease), or if you have taken them in the last 14 days. 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 treat nausea)

The risk of side effects is greater if you take Larapam SR Tablets at the same time as:

- sedative medicines such as benzodiazepines or related medicines (e.g. tranquillizers, sleeping pills). Concomitant use of Larapam SRLarapam SR and sedative medicines such as benzodiazepines or related medicines 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 **Larapram SRLarapram SR** 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.

- Other sedative medicines such as antidepressants and other pain relievers such as morphine and codeine (also as cough medicine), and alcohol. You may feel excessively drowsy or feel that you might faint.
- medicines which may cause convulsions (fits), such as certain antidepressants or antipsychotics. The risk having a fit may increase if you take Larapam SR Tablets at the same time. Your doctor will tell you whether Larapam SR Tablets is suitable for you.
- certain antidepressants. Larapam SR Tablets may interact with these medicines and you may experience serotonin syndrome (see section 4 "Possible side effects"). 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.
- gabapentin or pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain).

Larapam SR Tablets with food and alcohol

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

Food does not influence the effect of Larapam SR Tablets (see section 3 "How to take Larapam SR Tablets").

Pregnancy, breast-feeding and fertility

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

There is very little information regarding the safety of tramadol in human pregnancy, therefore you should not take Larapam SR Tablets if you are pregnant.

Chronic use of Larapam SR Tablets during pregnancy may lead to withdrawal symptoms in newborns.

Breast-feeding

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

Fertility

Based on human experience tramadol hydrochloride is suggested not to influence female or male fertility.

Driving and using machines

This medicine may cause side effects such as dizziness, 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 this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using Larapam SR, when and how long you need to take it, when to contact your doctor, and when you need to stop it (see also section 2).

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

The recommended doses are given below. Your doctor may gradually increase or decrease your dose depending on how you respond to the treatment.

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.

It is important that you do not continue to take this medicine for longer than absolutely necessary.

Adults and children aged 12 years and over:

- The recommended initial dose is 100 mg twice daily.
- Take one prolonged-release 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.

Use in children under 12 years:

This medicine is not recommended in children under 12 years.

Elderly:

- In elderly people (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 Larapam SR Tablets. If in your case the insufficiency is mild or moderate, your doctor may recommend prolonging the dosage interval.

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

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). Withdrawal symptoms can be the following: You may feel agitated, anxious, nervous or shaky. You 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). Further unusual CNS symptoms, i.e. confusion, delusions, change of perception of the own personality (depersonalization), and change in perception of reality (derealisation) and delusion of persecution (paranoia) have been seen very rarely. If you experience any of these complaints after you stop taking Larapam SR Tablets, 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, this medicine 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 (may affect up to 1 in 1,000 people). 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 swallowing or hives together with difficulty in breathing or dizziness
- swelling of the face, tongue and/or throat

Other possible side effects

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

Very common: may affect more than 1 in 10 people

- feeling sick (nausea)
- dizziness

Common: may affect up to 1 in 10 people

- headache
- drowsiness, tiredness
- constipation, dry mouth, vomiting
- sweating

Uncommon: may affect up to 1 in 100 people

- faster, stronger or irregular heartbeat, collapse or a fall in blood pressure on standing up, which causes dizziness, light-headedness or fainting
- These side effects may particularly occur in patients in an upright position or under physical strain. urge to vomit (retching), a feeling of pressure in the stomach, stomach bloating, diarrhoea

- itching, rash, and raised, red, itchy skin rash (hives)

Rare: may affect up to 1 in 1,000 people

- slower heartbeat
- rise in blood pressure
- changes in appetite
- tingling or numbness in the hands and feet
- tremor
- epileptic fits: occurred mainly after the use of high doses of tramadol or when tramadol was taken at the same time as other medicines which may induce fits
- difficulty sleeping, nightmares
- hallucinations, confusion, delirium, anxiety
- Psychological complaints may appear after treatment with Larapam SR Tablets. Their intensity and nature may vary (according to the patient's personality and length of therapy). These may appear as a change in mood (mostly high spirits, occasionally irritated mood), changes in activity (usually suppression, occasionally increase) and decreased cognitive and sensory perception (changes in senses and recognition, which may lead to errors in judgment).

- slow breathing, shortness of breath (dyspnoea)

If the recommended doses are exceeded, or if other medicines that depress brain function are taken at the same time, breathing may slow.

- worsening of asthma has been reported, however it has not been established whether it was caused by tramadol.
- blurred vision
- constriction of the pupil (miosis)
- widening of the pupils (mydriasis)
- weak muscles
- dependence (addiction): Withdrawal symptoms may occur when treatment is stopped (see section 3 "If you stop taking Larapam SR Tablets").
- involuntary muscle contractions
- lack of coordination
- transient loss of consciousness (syncope)
- speech disorders
- passing urine with difficulty or pain, excretion of less urine than normal

Very rare: may affect up to 1 in 10,000 people

- blood tests which show changes in the way the liver is working

Not known: frequency cannot be estimated from the available data

- 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 Larapam SR Tablets")
- decrease in blood sugar level

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 the Yellow Card Scheme (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 Larapam SR Tablets

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

Store this medicine in a safe and secure storage space, where other people cannot access it. It can cause serious harm and be fatal to people when it has not been prescribed for them.

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

Do not store Larapam SR Tablets above 25°C.

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 Larapam SR Tablets contains

- The active substance is tramadol hydrochloride.
- Each prolonged-release tablet contains 100, 150 or 200 mg tramadol hydrochloride.
- The other ingredients are: calcium hydrogen phosphate dihydrate (E341), colloidal anhydrous silica (E551), hypolose (E463), magnesium stearate (E470b).

What Larapam SR Tablets looks like and contents of the pack

Larapam SR Tablets 100 mg, prolonged-release tablets are off white, round and biconvex tablets.

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

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

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

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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