Package leaflet: Information for the user

Tradol SR 150 mg 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 of the 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 Tradol SR is and what it is used for

Tramadol, the active substance in Tradol SR, 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.

Tradol SR is used in the treatment of moderate to severe pain.

2. What you need to know before you take Tradol SR

Do not take Tradol SR
- if you are allergic to tramadol or any of the other ingredients of this medicine (listed in section 6)
- 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). The combination could result in a serious, potentially life-threatening interaction (see “Other medicines and Tradol SR”).
- if you have epilepsy that is not controlled with your current medicine
- as a drug substitute for the treatment of drug addiction.

Warnings and precautions

Talk to your doctor or pharmacist before taking Tradol SR 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 disease 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 pastsuffer from depression and you are taking antidepressants as some of them may interact with tramadol (see 'Other medicines and Tradol 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').

Sleep-related breathing disorders
Tradol 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.

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 Tradol SR. 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, Tradol SR 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 develop while you are taking this medicine and if you have experienced such problems in the past.

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.

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

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

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 Tradol SR at the same time. Your doctor will tell you whether Tradol SR is suitable for you.
- if you are taking certain antidepressants. Tradol SR may interact with these medicines and you may experience serotonin syndrome (see section 4 'Possible side effects').
- if you are taking 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.
- if you are taking 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.

Do not take Tradol SR 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.
Concomitant use of Tradol SR 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 Tradol 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.

Tradol SR with food and drink
Do not drink alcohol while taking Tradol SR; this could enhance the effects of the 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.

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

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

Tradol SR contains lactose
This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Tradol SR contains sodium
This medicine contains less than 1 mmol sodium (23mg) per dose, that is to say essentially 'sodium free'**.**

3 How to take Tradol SR

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 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 dose is 1 tablet twice daily, preferably in the morning and evening.

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:
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 Tradol SR without talking to their doctor. If in your case the insufficiency is mild or moderate, your doctor may recommend prolonging the dosage interval.

If you take more Tradol SR 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 Tradol SR 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 Tradol SR
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 Tradol SR
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) such as restlessness, anxiety, nervousness, insomnia, hyperactivity, tremor or gastrointestinal upset. Other symptoms which have very rarely been seen include panic attacks, severe anxiety, hallucinations, abnormal skin sensations (such as tingling, pins and needles and numbness) and noise in the ears. If you experience any of these side effects when you stop taking Tradol 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, 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 (affects less than 1 in 1000 people). Tell your doctor straightaway 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 bother 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
- being sick (vomiting), constipation, dry mouth
- sweating
- fatigue

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
- retching, a feeling of pressure in the stomach, stomach bloating
- diarrhoea
- pruritus, 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
- speech disorders
- tingling or numbness in the hands and feet
- tremor
- slow breathing
- epileptic-like seizures
- muscle twitches, uncoordinated movements
- transient loss of consciousness (syncope)
- difficulty sleeping, nightmares
- mood changes
- changes in activity (usually reduced, sometimes increased)
- changes in sensory perception and impairment of the ability to recognise, which can lead to inappropriate decisions
- hallucinations, confusion, delirium
- anxiety
- breathing difficulties
- worsening of asthma has been reported but it has not been established whether it was caused by tramadol
- blurred vision
- dilation or contraction of pupils
- reduced muscle strength
- passing urine with difficulty or pain, producing less urine than normal
- drug dependence (addiction); withdrawal symptoms may occur when treatment is stopped (see ‘if you stop taking Tradol SR’).

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)

- decrease in blood sugar level
- 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 Tradol SR').

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 HPRA Pharmacovigilance, website: www.hpra.ie; By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Tradol 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 carton and blister after 'Do not use after' or 'EXP'. The expiry date refers to the last day of that month.

Do not store 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 Content of the pack and other information

What Tradol SR contains

- The active substance is **tramadol hydrochloride**.
- One Tradol SR 150 mg Prolonged release tablet contains 150 mg tramadol hydrochloride.
- The other ingredients are lactose monohydrate, hypromellose, povidone, calcium hydrogen phosphate dihydrate, maize starch, microcrystalline cellulose, sodium starch glycolate, magnesium stearate, colloidal anhydrous silica, hydrogenated castor oil, indigotine (E132), quinolone yellow (E104), aluminium hydroxide and water.

What Tradol SR looks like and contents of the pack
Tradol SR is available in packs with 30 and 60 prolonged release tablets.

Not all pack sizes may be marketed.

Tradol SR 150 mg Prolonged release tablets are flat, round, bi-layered with a facet. The initial layer is white and the slow-release layer is green with a one-sided identification mark TR/150R.

Marketing Authorisation Holder
Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers
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This leaflet was last approved in July 2021.