

Package leaflet: Information for the user

Tradol 50mg Hard Capsules

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 is and what it is used for
2. What you need to know before you take Tradol
3. How to take Tradol
4. Possible side effects
5. How to store Tradol
6. Contents of the pack and other information.

1 What Tradol is and what it is used for

Tramadol, the active substance in Tradol, is a painkiller belonging to the class of opioids that acts on the central nervous system. It relieves pain by acting on specific nerve cells of the spinal cord and brain.

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

2. What you need to know before you take Tradol

Do not take Tradol

- 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 pills, pain relievers or other psychotropic medicines (medicines that affect mood, emotions)
- if you are also taking MAO inhibitors (certain medicines used for the treatment of depression) or have taken them in the last 14 days before treatment with Tradol (see 'Other medicines and Tradol')
- if you are an epileptic and your fits are not adequately controlled by treatment
- as a substitute in drug withdrawal.

Warnings and precautions

Talk to your doctor or pharmacist before taking Tradol if you

- think you are addicted to other pain relievers (opioids)
- suffer from consciousness disorders (if you feel that you are going to faint)

- are in a state of shock (cold sweat may be a sign of this)
- have difficulty in breathing
- suffer from increased pressure in the brain (possibly after a head injury or brain disease)
- suffer from a liver or kidney disease
- have a tendency towards epilepsy or fits because the risk of a fit may increase
- suffer from depression and you are taking antidepressants as some of them may interact with tramadol (see 'Other medicines and Tradol').

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 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 when doses of tramadol exceed the recommended upper daily dose limit (400 mg).

Please note that Tradol may lead to psychological and physical addiction. When taken for a long time, its effects may decrease, so that higher doses have to be taken (tolerance development). In patients with a tendency to abuse medicines or who are dependent on medicine treatment with Tradol should only be carried out for short periods and under strict medical supervision.

Please also inform your doctor if one of these problems occurs during Tradol treatment or if they applied to you in the past.

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 or pharmacist if you experience any of the following symptoms while using Tradol

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

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

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

Tradol should not be taken together with MAO inhibitors (certain medicines for the treatment of depression).

The pain-relieving effect of Tradol may be reduced and the length of time it acts may be shortened, if you take medicines which contain:

- carbamazepine (for epileptic fits)
- ondansetron (prevents nausea).

Your doctor will tell you whether you should take Tradol, and which 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 Tradol at the same time. Your doctor will tell you whether Tradol is suitable for you.
- if you are taking certain antidepressants. Tradol may interact with these medicines and you may experience serotonin syndrome (see section 4 'Possible side effects').
- if you are taking tranquillizers, sleeping pills, other pain relievers such as morphine, codeine (also as cough medicine), and alcohol while you are taking Tradol. You may feel drowsier or feel that you might faint. If this happens tell your doctor.
- if you are taking coumarin anticoagulants (medicines for blood thinning), e.g. warfarin, together with Tradol. The effects of these medicines on blood clotting may be affected and bleeding may occur.

Concomitant use of Tradol 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 with food and drink

Do not drink alcohol during treatment with Tradol; as its effect may be intensified. Food does not influence the effect of Tradol.

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 if you are pregnant.

Breast-feeding

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

Driving and using machines

This medicine may cause side effects such as drowsiness, dizziness and blurred vision and therefore may impair your reactions. If you feel that your reactions are affected, do not drive, do not use electric tools or operate machinery.

Tradol contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3 How to take Tradol

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. Do not take more than 400 mg tramadol hydrochloride daily, except if your doctor has instructed you to do so.

Swallow the capsules whole with a glass of water. Do not break or chew the capsules. The capsules 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 or 2 capsules every 4-6 hours.

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 suitable for 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. If in your case the insufficiency is mild or moderate, your doctor may recommend prolonging the dosage interval.

If you take more Tradol than you should

If you have taken an additional dose by mistake, this will generally have no negative effects. You should take your next dose as prescribed.

If you (or someone else) swallow a lot of Tradol at the same time you should go to hospital or call a doctor straight away. Signs of an overdose include very small pupils, being sick, fall in blood pressure, rapid heartbeat, collapse, unconsciousness, fits and breathing difficulties or shallow breathing.

If you forget to take Tradol

If you forget to take Tradol, pain is likely to return. Do not take a double dose to make up for a forgotten dose, simply continue taking Tradol as before.

If you stop taking Tradol

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 feeling agitated, anxious, nervous or shaky. They 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 “ringing” in the ears (tinnitus). Further unusual CNS symptoms, i.e. confusion, delusions, change of perception of the own personality (depersonalisation), 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 stopping Tradol, 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 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 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)

- effects on the heart and blood circulation (pounding of the heart, fast heartbeat, feeling faint or collapse). These adverse effects may particularly occur in patients in an upright position or under physical strain
- urge to be sick (retching), stomach trouble (e.g. feeling of pressure in the stomach, bloating), diarrhoea
- skin reactions (e.g. itching, rash)

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
- trembling
- slow breathing
- epileptic fits
- 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 errors in judgement
- 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
- weak muscles
- passing urine with difficulty or pain, producing less urine than normal
- drug dependence may occur. When treatment is stopped abruptly, signs of withdrawal may appear (see ‘if you stop taking Tradol’).

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’).

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

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. 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 Contents of the pack and other information

What Tradol contains

- The active substance is tramadol hydrochloride.
- One Tradol 50mg Hard Capsule contains 50 mg tramadol hydrochloride
- The other ingredients are calcium hydrogen-phosphate dihydrate, sodium starch glycolate Type A, magnesium stearate, titanium dioxide (E171), yellow ferric oxide (E172), gelatin, indigotin (E132).

What Tradol looks like and contents of the pack

Tradol is available in packs with 10 and 100 capsules.

Not all pack sizes may be marketed.

Tradol 50mg Hard Capsules are size 3 gelatin hard capsules with a green cap and a yellow body containing a white odourless powder.

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, D-39179 Barleben, Germany

Rowa Pharmaceuticals Ltd., Bantry, Co. Cork, Ireland.

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