

Package leaflet: information for the user

tramadol cinfa 50 mg 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 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

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2. What you need to know before you take tramadol cinfa
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1. What tramadol cinfa is and what it is used for

Tramadol, the active substance of this medicine, is an analgesic belonging to group of opioids that act on the central nervous system. It relieves pain by acting on specific nerve cells in the spinal cord and brain.

Tramadol cinfa is used in the treatment of moderate to severe pain.

2. What you need to know before you take tramadol cinfa

Do not take tramadol cinfa:

- If you are allergic to tramadol or any of the other ingredients of this medicine (listed in section 6).
- In cases of acute poisoning with alcohol, sleeping pills, pain relievers or other psychotropic medicines (medicines that act on mood and emotions).
- If you are taking MAOIs (a certain type of medicines used to treat depression) or you have taken them in the last two weeks before treatment with this medicine (see the section "Other medicines").
- If you suffer from epilepsy and your seizures are not adequately controlled with treatment.
- For the treatment of withdrawal syndrome.

Warnings and precautions

Talk to your doctor or pharmacist before taking tramadol cinfa:

- If you think you are dependent on other analgesics (opioids).
- If you have consciousness disorders (if you think you are going to faint).
- If you are in a state of shock (cold sweat may be a sign of this).
- If you suffer from increased pressure in the brain (for example after a head injury or brain disease).
- If you have difficulty breathing.
- If you are epileptic or suffer seizure episodes, because the risk of a seizure may increase.
- If you suffer from a liver or kidney disease.

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 limit (400 mg).

Take into account that tramadol can lead to physical and psychological addiction. When this medicine is taken for a long time, its effect may decrease, so higher doses have to be taken (tolerance development). In patients with a tendency to abuse medicines or who are dependent on medicines, treatment with tramadol 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 treatment with this medicine 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 each person in different ways. In some people, it is possible that sufficient pain relief is not achieved, while other people are more likely to suffer serious adverse effects. If you experience any of the following serious side effects, stop taking this medicine and seek immediate medical attention: slow or shallow breathing, confusion, drowsiness, pinpoint pupils, general malaise or vomiting, constipation, loss of appetite.

Children and adolescents

Use in children with respiratory problems:

The use of tramadol in children with respiratory problems is not recommended, since the symptoms of tramadol toxicity may worsen in these children.

Other medicines and tramadol can lead to

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

Tramadol should not be taken together with MAOIs (a certain type of medicines used to treat depression).

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

- Carbamazepine (for epileptic seizures)
- Ondansetron (to prevent nausea)

Your doctor will tell you whether you should take this medicine and at what dose. The risk of side effects increases:

- If you are taking this medicine simultaneously with tranquillisers, sleeping pills, other pain relievers such as morphine and codeine (even when used for treatment of cough) and alcohol. In these cases, you may feel drowsy or dizzy. If this happens tell your doctor. The concomitant use of tramadol with sedatives or medicines for treating insomnia (such as benzodiazepine) increase the risk of drowsiness, difficulty breathing (respiratory depression), coma and may potentially be fatal. For this reason, concomitant use should only be considered when other treatment options are not possible. Nevertheless, if your doctor prescribes you tramadol with sedative medicines, the dose and duration of treatment must be limited. Tell your doctor about all sedative medicines that you are taking and follow your doctor's dose recommendations strictly. It may be useful to inform your friends and family about the signs and symptoms indicated above. Tell your doctor if you experience these symptoms.
- If you are taking medicines that facilitate or may cause seizures, such as certain antidepressants or antipsychotics. The risk of having seizure episodes may increase if you take tramadol at the same time as these medicines. Your doctor will tell you whether tramadol is suitable for you.
- If you are taking medicines to treat depression, tramadol can interact with these medicines and you may experience symptoms such as involuntary rhythmic muscle contractions, including the muscles that control the movement of the eyes, agitation, excessive perspiration, tremor, exaggerated reflexes, increased muscle tension, body temperature above 38°C.

- If you are taking coumarin anticoagulants (medicines for blood thinning) e.g. warfarin, while taking tramadol. The effect of these medicines on blood clotting may be affected and bleeding may occur.
- If you take medicines that can increase the accumulation of tramadol and, therefore, its adverse effects (such as ritonavir, quinidine, paroxetine, fluoxetine, sertraline, amitriptyline, isoniazid, ketoconazole and erythromycin).

Tramadol cinfa with food and alcohol

Do not consume alcohol during treatment with this medicine, as its effect may be intensified. Food does not influence the effect of tramadol.

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.

There is very little information regarding the safety of tramadol in human pregnancy. Therefore, you should not use this medicine if you are pregnant.

Chronic treatment during pregnancy may lead to withdrawal symptoms in newborns.

Tramadol is excreted in breast milk. For this reason, you should not take tramadol cinfa more than once while breast-feeding, or if you take tramadol cinfa more than once, you should stop breast-feeding.

Based on experience in humans, tramadol is suggested not to influence male or female fertility.

Driving and using machines

Ask your doctor whether you can drive or use machinery during treatment with tramadol. It is important that you know how this medicine affects you before driving or operating machinery. Do not drive or use machinery if you feel sleepy, dizzy, have blurred or double vision, or have trouble concentrating. Take special care at the start of treatment, after an increase in dose, after a change in formulation and/or when it is administered together with other medications.

3. How to take tramadol cinfa

Always take this medicine exactly as your doctor or pharmacist 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, unless your doctor has instructed you to do so.

Unless your doctor has told you otherwise, the normal dose is:

Adults and adolescents over 12 years of age

Normally the initial dose is 1-2 capsules (50-100 mg tramadol hydrochloride). Depending on the pain, the effect may last 4-6 hours.

Use in children

This medicine is not recommended for children under 12 years of age.

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.

Patients with liver or kidney failure and patients on dialysis

If you suffer from any serious liver or kidney disease, treatment with this medicine is not recommended. If your liver or kidney insufficiency is moderate, your doctor may prolong the dosage intervals.

How and when should you take tramadol cinfa?

The capsules are administered orally.

Swallow the capsules whole, without dividing or chewing them and with sufficient liquid. You can take this medicine on an empty stomach or with meals.

How long should you take tramadol cinfa?

This medicine must not be administered for longer than is strictly necessary. If you need to be treated for a longer period, your doctor will check at regular short intervals (if necessary with breaks in treatment) whether you should continue to with the treatment and at what dose.

If you think the effects of this medicine are too strong or too weak, tell your doctor or pharmacist.

If you take more tramadol cinfa 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.

Taking very high doses of tramadol can cause the pupils to contract, vomiting, a fall in blood pressure, fast heart beat, collapse, decreased level of consciousness to coma (deep unconsciousness), epileptic fits and breathing difficulties that can lead to respiratory arrest. If this occurs, call a doctor immediately.

In case of overdose or accidental ingestion, tell your doctor or pharmacist immediately, specifying the medicine and the amount ingested.

If you forget to take tramadol cinfa

If you forget to take this medicine, the pain is likely to return. Do not take a double dose to make up for the forgotten doses, just continue to take tramadol as you have been doing so far.

If you stop taking tramadol cinfa

If you interrupt or finish treatment with this medicine too soon, the pain is likely to return. If you want to stop the treatment due to the adverse effects, consult your doctor.

You should not suddenly stop taking this medication unless your doctor tells you to. If you want to stop taking your medicine, talk to your doctor first, especially if you have been taking it for a long time. Your doctor will tell you when and how to stop it, which can be done by gradually reducing the dose to reduce the likelihood of unnecessary side effects (withdrawal symptoms).

Generally, there will be no adverse effects when treatment with tramadol is stopped. Nevertheless, on rare occasions, people who have been taking this medicine for some time may feel unwell if they stop the treatment abruptly. They may feel agitated, anxious, nervous or shaky. They may be hyperactive, have difficulty sleeping and problems with digestion and intestinal transit. Very few people may get panic attacks, hallucinations, unusual perceptions such as itching, tingling and numbness, and “ringing” in the ears (tinnitus). Very rarely, more unusual symptoms of the central nervous system have been detected such as confusion, delusions, change of personality perception (depersonalisation), and change in the perception of reality (derealisation) and delusions of persecution (paranoia). If you experience any of these symptoms after stopping treatment with this medicine, 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.

Consult your doctor immediately if you present symptoms of an allergic reaction such as swelling of the face, tongue and/or throat and/or difficulty swallowing and rash in conjunction with shortness of breath.

The most common adverse effects during treatment with tramadol are nausea and dizziness, which occur in more than 1 in 10 people.

Very common: may affect more than 1 in 10 people

- Dizziness.
- Nausea.

Common: may affect up to 1 in 10 people

- Headache and drowsiness.
- Fatigue.
- Constipation, dry mouth, vomiting.
- Sweating (hyperhidrosis).

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 fullness, bloating), diarrhoea.
- Skin reactions (for example, itching, skin rash).

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

- Allergic reactions (e.g. difficulty in breathing, wheezing, swelling of skin) and shock (sudden circulatory collapse) have occurred in very rare cases.
- Slow heart beat.
- Increase in blood pressure.
- Abnormal sensations (e.g. itching, tingling, numbness), trembling, epileptic fits, muscle twitches, uncoordinated movement, transient loss of consciousness (syncope), speech disorders.
- Epileptic fits have occurred mainly after the use of high doses of tramadol or when it was taken at the same time as other medicines which may induce fits.
- Changes in appetite.
- Hallucinations, confusional state, sleep disorders, delirium, anxiety and nightmares.
- Psychological disturbances may appear after treatment with tramadol cinfa. Their intensity and nature may vary (according to the patient's personality and length of treatment). These may appear as a change in mood (mostly high spirits, occasionally irritated mood), changes in activity (usually decrease and occasionally increase) and decreased cognitive and sensory perception (alterations of the senses and perception that can lead to errors of judgement).
- Dependence on the medicine may occur.
- When treatment is stopped abruptly, abstinence syndrome may occur (see "If you stop treatment with tramadol cinfa").
- Blurred vision, contraction of the pupils (miosis), excessive dilation of the pupils (mydriasis).
- Slow breathing, shortness of breath (dyspnoea).
- Worsening of asthma has been reported, however it has not been established whether it was caused by tramadol. If the recommended doses are exceeded, or if other medicines that depress brain function are taken at the same time, there may be a reduction of the breathing rate.
- Muscle weakness.
- Difficulty or pain passing urine, passing less urine than normal (dysuria).

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

- Increased liver enzymes.

Not known: frequency cannot be estimated from the available data

- Decreased blood sugar levels.

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. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store tramadol cinfa

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

Please store below 25°C.

Do not use this medicine after the expiry date which is stated on the container after “EXP”. The expiry date refers to the last day of that month.

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 tramadol cinfa contains

- The active substance is tramadol. Each capsule contains 50 mg of tramadol hydrochloride.
- The other ingredients are:
 - Content of the capsule: calcium hydrogen phosphate, magnesium stearate, colloidal anhydrous silica.
 - Hard gelatin capsule: the gelatine capsule is made up of gelatin, titanium dioxide (E171), yellow iron oxide (E172) and indigo carmine (E132).

What the product looks like and contents of the pack

- Tramadol cinfa comes in the form of capsules with an opaque green cap and opaque yellow body, containing a white odourless powder.
- Each pack contains 20 or 60 capsules in aluminium/PVC blisters. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Laboratorios Cinfa, S.A.
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Industrial Areta, 31620, Huarte (Navarra)
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