

**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**

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

**1. What tramadol cinfa is and what it is used for**

Tramadol is an opioid analgesic that acts on the central nervous system. It relieves pain by acting on specific nerve cells in the spinal cord and brain.

Tramadol cinfa is indicated 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 (hypersensitive) 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 and emotions).
- If you are taking, or you have taken in the last two weeks before treatment with tramadol cinfa, monoamine oxidase inhibitors (MAOIs), these are medicines to treat depression (see the section “ Other medicines and tramadol cinfa”).
- If you are suffering from uncontrolled epilepsy.
- For the treatment of withdrawal syndrome.

**Warnings and precautions**

Talk to your doctor before taking tramadol cinfa:

- If you think you have dependence on other potent analgesics (opioids).
- If you suffer from 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 in 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 (400mg). 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: slowed or shallow breathing, confusion, drowsiness, pinpoint pupils, general malaise or vomiting, constipation, loss of appetite.

Please note that tramadol cinsa may lead to physical and psychological addiction.

When tramadol cinsa is taken for a long time, its effect 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 medicines, treatment with tramadol cinsa 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 tramadol cinsa or if they applied to you in the past.

### **Other medicines and tramadol cinsa**

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 monoamine oxidase inhibitors (MAOIs), certain medicines for the treatment of depression.

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

- Carbamazepine (for epileptic fits).
- Ondansetron (to prevent nausea).

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

- if you are taking tramadol cinsa simultaneously with tranquillizers, 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.
- if you are taking medicines that facilitate or which may cause seizure episodes, such as certain antidepressants or antipsychotics. The risk of having seizure episodes may increase if you take tramadol cinsa at the same time as these medicines. Your doctor will tell you whether tramadol cinsa

is suitable for you.

- If you are taking medicines for the treatment of depression, tramadol cinsa may interact with these medicines and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, excessive sweating, tremor, exaggeration of 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 cinsa. The effect of these medicines on blood clotting may be affected and bleeding may occur.
- If you take drugs that can increase the accumulation of tramadol cinsa and, therefore, its adverse effects (such as ritonavir, quinidine, paroxetine, fluoxetine, sertraline, amitriptyline, isoniazid, ketoconazole and erythromycin).

### **Tramadol cinsa with food and alcohol**

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

### **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 tramadol cinsa if you are pregnant.

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

Tramadol is excreted in breast milk. For this reason, you should not take tramadol cinsa more than once during lactation, or if you take tramadol cinsa more than once, you should stop breastfeeding.

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 cinsa**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have 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 400mg tramadol hydrochloride daily, unless your doctor has instructed you to do so.

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

**Use in adults and adolescents over 12 years of age**

Normally the initial dose is 1-2 capsules of tramadol cinfa (50-100 mg tramadol hydrochloride) followed by 1-2 capsules every 6-8 hours. Do not take more than 8 capsules of tramadol cinfa (400 mg) daily. Depending on the pain, the effect lasts between 4 and 8 hours.

**Use in children and adolescents**

tramadol cinfa is not recommended for children under 12 years of age.

**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.

**Use in 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 tramadol cinfa 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 of tramadol cinfa are administered orally.

The capsules should be swallowed whole, without dividing or chewing them and with sufficient liquid. You may take tramadol cinfa on an empty stomach or with meals.

*How long should you take tramadol cinfa?*

Tramadol cinfa should not be administered for longer than 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 take Tramadol and at what dose.

If you have the impression that the effect of tramadol cinfa is 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, notify your doctor or pharmacist immediately specifying the medicine and the amount taken. It is recommended to take the leaflet of the medicine to the healthcare provider.

#### **If you forget to take tramadol cinfa**

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

#### **If you stop taking tramadol cinfa**

If you interrupt or finish treatment with Tramadol too soon, the pain is likely to return. 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 after-effects when treatment with tramadol cinfa is stopped. However, on rare occasions, people who have been taking tramadol cinfa 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 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 tramadol cinfa, consult your doctor.

If you have any further question 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.

**Ask your doctor immediately if you develop symptoms of an allergic reaction such as swelling of your face, tongue, and/or throat and/or difficulty swallowing and rash along with difficulty breathing.**

Very common: may affect more than 1 out of every 10 people

- Dizziness
- Nausea.

Common: may affect up to 1 in 10 people

- Headache and drowsiness.
- Fatigue.
- Vomiting, constipation and dry mouth.

- 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 (e.g. Itching, 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).
- 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).
- Drug dependence may occur. If tramadol is used for long periods of time, it can lead to dependency, although the risk is very low.
- When treatment is stopped abruptly, abstinence syndrome may occur (see "If you stop treatment with tramadol cinfa").
- Blurred vision, excessive dilation of the pupils (mydriasis), constriction of the pupil (miosis).
- 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.

Frequency not known: the frequency cannot be estimated from the available data:

- 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.

### **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 tramadol cinfa after the expiry date stated on the pack 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: anhydrous 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 tramadol looks like and contents of the pack**

Each package contains 20 capsules

#### **Marketing Authorisation Holder and Manufacturer:**

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**This leaflet was last revised in: July 2018.**