

Tramadol 50 mg 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 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 is and what it is used for
2. What you need to know before you take Tramadol
3. How to take Tramadol
4. Possible side effects
5. How to store Tramadol
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1. What Tramadol is and what it is used for

The active substance in Tramadol 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.

Tramadol capsules are used for the treatment of moderate to severe pain in adults and children aged 12 years and over.

2. What you need to know before you take Tramadol

Do not take Tramadol:

- 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 medicines that affect mood and emotions;
- if you are also taking MAO inhibitors (certain medicines used for treatment of depression) or have taken them in the last 14 days before treatment with Tramadol (see "Other medicines and Tramadol");
- if you suffer from epilepsy 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 Tramadol:

- if you think that you are addicted to other pain relievers (opioids);
- if you suffer from consciousness disorders (if you feel that 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 (possibly after a head injury or brain disease);
- if you have difficulty in breathing;
- if you have a tendency towards epilepsy or fits because the risk of a fit 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 dose limit (400 mg).

Please note that Tramadol may lead to physical and psychological addiction. When Tramadol 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 drug abuse or drug

dependance, 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 Tramadol treatment or if they applied to you in the past.

Other medicines and Tramadol

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 MAO inhibitors (certain medicines for the treatment of 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 fits);
- ondansetron (prevents nausea).

Your doctor will tell you whether you should take Tramadol, and which dose.

The risk of side effects increases,

- if you are taking tranquillizers, sleeping pills, other pain relievers such as morphine and codeine (also as cough medicine), and alcohol while you are taking Tramadol . You may feel drowsier or feel that you might faint. If this happens tell your doctor.
- if you are taking medicines which may cause convulsions (fits), such as certain antidepressants or antipsychotics. The risk having a fit may increase if you take Tramadol at the same time. Your doctor will tell you whether Tramadol is suitable for you.
- if you are taking certain antidepressants Tramadol 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 that prevent blood clotting), e.g. warfarin, together with Tramadol.

The effect of these medicines on blood clotting may be affected and bleeding may occur.

Tramadol with food and alcohol

Do not drink alcohol during treatment with Tramadol as its effect may be intensified.

Food does not influence the effect of Tramadol .

Pregnancy and breast-feeding and fertility Pregnancy

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 during pregnancy in human. Therefore you should not use Tramadol if you are pregnant.

Chronic use of Tramadol during pregnancy may lead to tramadol dependance in the unborn child and consequently to withdrawal symptoms in newborns.

Breast-feeding

Generally, the use of tramadol is not recommended during breast-feeding. Very small amounts of tramadol are excreted into breast milk. After a single dose it is usually not necessary to interrupt breast-feeding. Ask your doctor for advice.

Fertility

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

Driving and using machines

Tramadol may cause drowsiness, dizziness and visual disturbances (blurred vision) and therefore may impair your reactions. If you feel that your reactions are affected, do not drive a car or other vehicle, do not use electric tools or operate machinery.

Tramadol 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 Tramadol

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 8 capsules of Tramadol daily (which is equivalent to 400 mg tramadol hydrochloride), except if your doctor has instructed you to do so.

Unless otherwise prescribed by your doctor, the usual dose is:

Adults and adolescents from the age of 12 years

The usual dose is 1 or 2 capsules every 4-6 hours.

The recommended dose for moderate pain is 1 hard capsule of Tramadol (corresponding to 50 mg tramadol hydrochloride). If no pain relief occurs within 30 to 60 minutes, a second capsule can be taken.

A higher demand for pain relief may be expected for severe pain, in this case 2 hard capsules can be taken as a single dose of Tramadol (corresponding to 100 mg of tramadol hydrochloride).

Children

Tramadol capsules are not suitable for children below the age of 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 Tramadol. If in your case the insufficiency is mild or moderate, your doctor may recommend prolonging the dosage interval.

How and when should you take Tramadol?

Tramadol are for oral use.

Always swallow Tramadol whole, not divided or chewed, with sufficient liquid. You may take the capsule on an empty stomach or with meals.

How long should you take Tramadol?

You should not take Tramadol longer than 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 taking Tramadol and at what dose.

Please talk to your doctor or pharmacist if you have the impression that the effect of Tramadol is too strong or too weak.

If you take more Tramadol than you should

If you have taken an additional dose of Tramadol 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 Tramadol capsules at the same time you should go to hospital or call a doctor straight away. Signs of an overdose include very small pupils, vomiting, fall in blood pressure, rapid heartbeat, circulatory collapse, unconsciousness up to coma (deep unconsciousness), fits and breathing difficulties or shallow breathing up to respiratory arrest. If these signs occur, contact your doctor immediately.

If you forget to take Tramadol

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

If you stop taking Tramadol

If you interrupt or finish treatment with Tramadol too soon, pain is likely to return.

If you wish to stop treatment on account of unpleasant effects, please tell your doctor.

Generally there will be no after-effects when treatment with Tramadol is stopped. However, on rare occasions, people who have

been taking Tramadol for some time may feel unwell if they abruptly stop taking them. They may feel 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 reported very rarely. If you experience any of these complaints after stopping Tramadol, 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.

You should see a doctor immediately if you experience symptoms of an allergic reaction such as swollen face, tongue and/or throat, and/or difficulty swallowing or hives together with difficulties in breathing.

Very common (may affect more than 1 in 10 people)

- dizziness
- feeling sick (nausea)

Common (may affect up to 1 in 10 people)

- headaches, drowsiness
- tiredness
- constipation, dry mouth, vomiting
- excessive sweating (hyperhidrosis)

Uncommon (may affect up to 1 in 100 people)

- effects on the heart and blood circulation (pounding of the heart, fast heartbeat (tachycardia), dizzy spells (orthostatic hypotension

or circulatory collapse). These adverse effects may particularly occur in patients when standing up and in patients 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)

- allergic reactions (e.g. difficulty breathing (dyspnoea), wheezing, water retention in tissues (angioedema) and shock reactions (sudden circulation failure) occur very rarely
- slow heartbeat (bradycardia)
- increase in blood pressure
- abnormal skin sensations (e.g. itching, tingling, numbness), trembling (tremor), involuntary muscle twitching, uncoordinated movement, transient loss of consciousness (syncope), speech disorders.
- Epileptic fits have occurred mainly at high doses of tramadol or when tramadol was taken at the same time as other medicines which may induce fits.

- changes in appetite
- hallucination, confusion, sleep disorders, anxiety and nightmares
- Psychological complaints may appear after treatment with Tramadol. 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 (being less aware and less able to make decisions, which may lead to errors in judgement).
- Drug dependence may occur. If Tramadol is taken over a long period of time dependence may occur, although the risk is very low. When treatment is stopped abruptly, signs of withdrawal may appear (see “If you stop taking Tramadol”).
- blurred vision, excessive dilation of the pupils (mydriasis), narrow pupils (miosis)

- slow breathing (respiratory depression), 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, breathing may slow down.
- weak muscles
- passing urine with difficulty or pain, passing less urine than normal (micturition disorders and dysuria)

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

- increased hepatic enzyme

Not known (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. You can also report side effects directly via Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tramadol

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 packaging after EXP. The expiry date refers to the last day of that month.

Do not store above 30 °C.

Store in the original package in order to protect from moisture.

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 contains

- The active substance is tramadol hydrochloride. Each hard capsule contains 50 mg tramadol hydrochloride.
- The other ingredients (excipients) are microcrystalline cellulose, sodium starch glycolate (type A), talc and magnesium stearate (E470b) in the capsule core and titanium dioxide (E171), indigo carmine (E132) and gelatin in the capsule shell.

What Tramadol looks like and contents of the pack

Hard capsules (capsules): the body of the capsule is white and the cap is blue. Capsules are filled with white or almost white powder. The size of the capsule is No: 4. The length of filled capsules is 14-15 mm.

Tramadol is available in boxes containing 10, 20, 30, 50, 60, 90 and 100 hard capsules in blisters.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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