

PATIENT INFORMATION LEAFLET

TRAMADOL HYDROCHLORIDE 50mg CAPSULES



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 (section 4).

In this leaflet:

1. What Tramadol Hydrochloride 50mg Capsules is and what it is used for
2. What you need to know before you take Tramadol Hydrochloride 50mg Capsules
3. How to take Tramadol Hydrochloride 50mg Capsules
4. Possible side effects
5. How to store Tramadol Hydrochloride 50mg Capsules
6. Contents of the pack and other information

1. What Tramadol Hydrochloride 50mg Capsules is and what it is used for

Tramadol - the active substance in Tramadol Hydrochloride 50mg Capsules - 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 Hydrochloride 50mg Capsules is used for the treatment and prevention of moderate to severe pain.

2. What you need to know before you take Tramadol Hydrochloride 50mg Capsules

Do not take Tramadol Hydrochloride 50mg Capsules,

- 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 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 Hydrochloride 50mg Capsules (see "Other medicines and Tramadol Hydrochloride 50mg Capsules");
- if you are an epileptic and your fits are not adequately controlled by treatment;
- are pregnant, planning to become pregnant or are breast-feeding
- as a substitute in drug withdrawal.

Warnings and precautions

Talk to your doctor before taking Tramadol Hydrochloride 50mg Capsules

- 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 have experienced dizziness while taking this medicine as it may increase the risk of falling
 - 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 or have a history of suffering from peptic (stomach) ulcers – tramadol hydrochloride may mask the effects of perforated ulcers;
 - 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 Hydrochloride 50mg Capsules may lead to physical and psychological addiction. When Tramadol Hydrochloride 50mg Capsules 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 Hydrochloride 50mg Capsules 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 Hydrochloride Capsules treatment or if they applied to you in the past.

Other medicines and Tramadol Hydrochloride 50mg Capsules

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

Tramadol Hydrochloride 50mg Capsules should not be taken together with MAO inhibitors (certain medicines for the treatment of depression) now or within the last two weeks, or any other medicines used for depression (e.g. amitriptyline, fluoxetine and lithium).

The pain-relieving effect of Tramadol Hydrochloride 50mg Capsules may be reduced and the length of time it acts may be shortened, if you take medicines which contain

- carbamazepine (for epileptic fits);
- pentazocine, nalbuphine or buprenorphine (pain killers);
- ondansetron (prevents nausea)
- warfarin (drug used to thin the blood).
- selective serotonin reuptake inhibitors (SSRIs) taken with tramadol hydrochloride may cause confusion, agitation, fever, sweating, unsteadiness, muscle rigidity or spasms and diarrhoea. These symptoms may be an indication of a serious disorder called serotonin syndrome. If you experience any of these symptoms contact your doctor immediately.

Your doctor will tell you whether you should take Tramadol Hydrochloride 50mg Capsules, and what dose.

The risk of side effects increases,

- if you take tranquilizers, sleeping pills, other pain relievers such as morphine and codeine (also as cough medicine), and alcohol while you are taking

Tramadol Hydrochloride 50mg Capsules. 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 Hydrochloride 50mg Capsules at the same time. Your doctor will tell you whether Tramadol Hydrochloride 50mg Capsules is suitable for you.
- if you are taking certain antidepressants, Tramadol Hydrochloride 50mg Capsules 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 take coumarin anticoagulants (medicines for blood thinning), e.g. warfarin, together with Tramadol Hydrochloride 50mg Capsules. The effect of these medicines on blood clotting may be affected and bleeding may occur.

Tramadol Hydrochloride 50mg Capsules with food and alcohol

Do not drink alcohol during treatment with Tramadol Hydrochloride 50mg Capsules as its effect may be intensified.

Food does not influence the effect of Tramadol Hydrochloride 50mg Capsules.

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 Hydrochloride 50mg Capsules if you are pregnant. Chronic use during pregnancy may lead to withdrawal symptoms in new-borns. Generally, the use of tramadol is not recommended during breast-feeding. Small amounts of tramadol are excreted into breast milk. On a single dose it is usually not necessary to interrupt breast-feeding. Please ask your doctor for advice.

Driving and using machines

This medicine may make you sleepy, confused, forgetful, unsteady, or affect your concentration or co-ordination. This may affect your performance at skilled tasks, e.g. driving or operating machinery. DO NOT drive or operate machinery if you are affected.

The medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
 - The medicine has been prescribed to treat a medical or dental problem and
 - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
 - It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Tramadol Important information about some of the ingredients of your medicine

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

3. How to take Tramadol Hydrochloride 50mg Capsules

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.

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

Adults and adolescents from the age of 12 years
One or two Tramadol Hydrochloride 50mg Capsules (equivalent to 50 mg – 100 mg tramadol hydrochloride).

Your doctor may prescribe a different, more appropriate dosage of Tramadol Hydrochloride 50mg Capsules if necessary.

Do not take more than 8 Tramadol Hydrochloride 50mg capsules (equivalent to 400 mg tramadol hydrochloride) daily, except if your doctor has instructed you to do so.

Children

Tramadol Hydrochloride 50mg Capsules is 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 Hydrochloride 50mg Capsules. 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 Hydrochloride 50mg Capsules:

Tramadol Hydrochloride 50mg Capsules are for oral use.

Always swallow Tramadol Hydrochloride 50mg Capsules whole, not divided or chewed, with sufficient liquid, preferably in the morning and evening. You may take the capsule on an empty stomach or with meals.

How long should you take Tramadol Hydrochloride 50mg Capsules?

You should not take Tramadol Hydrochloride 50mg Capsules for 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 to take.

Tramadol Hydrochloride 50mg Capsules and at what dose.

If you have the impression that the effect of Tramadol Hydrochloride 50mg Capsules is too strong or too weak, talk to your doctor or pharmacist.

If you take more Tramadol Hydrochloride 50mg Capsules 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 Tramadol Hydrochloride 50mg Capsules 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, a fall in blood pressure, a fast heartbeat, collapse, unconsciousness, fits and breathing difficulties or shallow breathing.

If you forget to take Tramadol Hydrochloride 50mg Capsules

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

If you stop taking Tramadol Hydrochloride 50mg Capsules

If you interrupt or finish treatment with Tramadol Hydrochloride 50mg Capsules 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 Hydrochloride 50mg Capsules is stopped. However, on rare occasions, people who have been taking Tramadol Hydrochloride 50mg Capsules for some time may feel unwell if they abruptly stop taking them. They may feel agitated, anxious, nervous or shaky. They may be confused, hyperactive, have difficulty sleeping and have stomach or bowel disorders. Very few people may get panic attacks, delusions, paranoia, hallucinations or feeling a loss of identity. They may experience unusual perceptions such as itching, tingling and numbness, and "ringing" in the ears (tinnitus). If you experience any of these complaints after stopping Tramadol Hydrochloride 50mg Capsules, please consult your doctor. If you have any further questions on the use of this product, 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.**

The most common side effects during treatment with Tramadol Hydrochloride 50mg Capsules 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 (feeling sick)

Common: may affect up to 1 in 10 people

- headaches, drowsiness, strong desire for sleep, or sleeping for unusually long periods
- tiredness, weariness, weakness, low energy
- constipation, dry mouth, vomiting (being sick)
- sweating

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 sick (retching), stomach trouble (e.g. feeling of pressure in the stomach, bloating), diarrhoea
- skin reactions (e.g. itching, rash)
- sudden fall in blood pressure
- flushing

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

- slow heartbeat; increase in blood pressure
- abnormal sensations (e.g. itching, tingling, numbness), trembling,
- epileptic fits, muscle twitches,
- uncoordinated movement, transient loss of consciousness (syncope).
- changes in appetite
- hallucination, confusional state, sleep disorders, delirium, anxiety and nightmares
- blurred vision
- 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, breathing may slow down.

- weak muscles
- passing water difficult or painful, less urine than normal.
- swelling of the skin
- dependence/withdrawal symptoms may occur
- diseased state of the blood, usually one in which the blood contains permanent abnormal cellular elements

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.

Psychological complaints may appear after treatment with Tramadol Hydrochloride 50mg Capsules. 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 (changes in senses and recognition, which may lead to errors in judgment). Drug dependence may occur. If Tramadol Hydrochloride 50mg Capsules 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 Hydrochloride 50mg Capsules").

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

- increase in liver enzyme values
- ringing of the ears

Not known: frequency cannot be estimated from the available data

- decrease in blood sugar level
- speech disorders
- dilated pupils

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tramadol Hydrochloride 50mg Capsules

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

Do not use this medicine after the expiry date which is stated on the carton and the blister. The expiry date refers to the last day of that month.

Store below 25° C in a dry place.

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 Hydrochloride 50mg Capsules looks like and contents of the pack

Tramadol Hydrochloride 50mg Capsules are green and yellow in colour and printed with "TRA 50".

Your medicine comes in pack sizes of **30, 50, 100, 250 and 500 capsules. Not all pack sizes may be marketed.**

What Tramadol Hydrochloride 50mg Capsules contains

Each capsule contains 50mg of tramadol hydrochloride, the active ingredient.

The capsules also contain the inactive ingredients microcrystalline cellulose, povidone, lactose monohydrate, sodium starch glycolate and magnesium stearate. The capsule shell contains gelatin and the colours titanium dioxide (E171), indigotine (E132), yellow iron oxide (E172) and erythrosin (E127). The ink on the capsule shell contains shellac, propylene glycol and the colour black iron oxide (E172).

MANUFACTURING AUTHORISATION HOLDER AND MANUFACTURER

Marketing Authorisation Holder

Athlone Pharmaceuticals Limited, Ballymurray, Co. Roscommon, Ireland.

Manufacturer responsible for batch release

Kent Pharmaceuticals Limited, Crowbridge Road, Ashford, Kent, TN24 0GR, U.K.
Kent Pharmaceuticals Limited, Repton Road, Measham, DE12 7DT, U.K.

Distributor

Kent Pharmaceuticals Limited, Repton Road, Measham, DE12 7DT, U.K.

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