

Tramadol 50 mg Capsules

Tramadol hydrochloride

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet

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

1. WHAT ARE TRAMADOL 50 mg CAPSULES AND WHAT ARE THEY USED FOR

Tramadol 50 mg Capsules are 'analgesics' which act on the central nervous system (the brain and the spinal cord). Analgesics are often called 'pain killers' or 'pain relievers'. Tramadol 50 mg Capsules relieve pain and can also be taken to prevent pain.

Pain is a symptom not an illness. There are many types of pain with many different causes, for example back-ache, toothache, pain after an operation or pain from broken bones.

Tramadol 50 mg Capsules help your body's system for relieving pain. It does this in two ways:

- Acts directly on parts of your brain and spinal cord to reduce the amount of pain you feel
- Reduces the size of the pain message passed from one nerve to another.

Tramadol 50 mg Capsules should only be taken by adults or children over 12.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TRAMADOL 50 mg CAPSULES

Do not take Tramadol 50 mg Capsules

- If you have had an allergic reaction, skin rash, swelling of the face, wheezing or difficulty breathing after taking tramadol or any of the other ingredients in Tramadol 50 mg Capsules
- If you are hypersensitive (allergic) to tramadol hydrochloride or any of the other ingredients in Tramadol 50 mg Capsules
- If you are pregnant or if you are breast-feeding
- If you are taking a monoamine oxidase inhibitor (MAOI) or have taken one in the past two weeks. You should know if you are taking MAOI because your doctor or chemist will have told you, and you may also have a treatment card
- If you suffer from epilepsy not controlled by treatment
- If you have drunk enough alcohol to make you feel woozy or drunk
- If you feel 'high' or excited because you have taken medicines that slow the nervous system. These medicines include tranquillisers, sleeping pills, psycho-tropic medicines (medicines that affect your mood or emotions) or other pain relievers such as morphine and codeine
- If you have severe kidney disease
- As a substitute in drug withdrawal.

Warnings and precautions

- 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 had a head injury or have brain disease. If you have a very bad headache or vomit without feeling sick first, this could be a sign of this
- If you suffer from epilepsy, convulsions or seizures (fits) or have had them in the past
- If you feel light-headed, faint, cold or clammy, or look pale
- If you suffer from asthma, or other lung disease or have difficulty in breathing

- If you suffer from kidney or liver disease.

In such cases please consult your doctor before taking the medicine.

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 50 mg Capsules may lead to physical and psychological addiction. When Tramadol 50 mg 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 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 Capsules treatment or if they applied to you in the past.

Taking other medicines

Tramadol Capsules should not be taken together with MAO inhibitors (certain medicines for the treatment of depression). The pain-relieving effect of Tramadol 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).

Please tell your doctor or pharmacist:

- If you are taking other medicines including tranquilizers, sleeping pills, antidepressants and other pain relievers such as morphine and codeine. You may feel drowsier or feel that you might faint.
- If you are going to be given a general anaesthetic tell your doctor or dentist that you are taking Tramadol 50 mg Capsules
- If you are taking carbamazepine, a treatment for epilepsy, this may reduce the pain relieving effect of Tramadol 50 mg Capsules. Your doctor will tell whether Tramadol 50 mg Capsules is suitable for you.
- If you are taking antidepressants these may cause convulsions (fits). The chance of having a fits is rare, but if you are also taking Tramadol 50 mg Capsules, the risk of having a fits may increase. Your doctor will tell you whether having Tramadol 50 mg Capsules is suitable for you
- If you are taking selective serotonin reuptake inhibitors (often referred to as SSRI's) or triptans or MAOI's because it has been shown that Tramadol may interfere with these medicine and you may experience symptoms such as confusion, restlessness, fever, sweating, uncoordinated movement of limbs or eyes, uncontrollable jerking of muscles, or diarrhoea.
- If you take coumarin anticoagulants (medicines for blood thinning), e.g. warfarin, together with Tramadol 50 mg Capsules. The effect of these medicines on blood clotting may be affected and bleeding may occur.
- If you are taking lithium, make sure your doctor or dentist knows. Tramadol 50 mg Capsules could alter the effect of lithium.
- If you are taking coumarin anticoagulants (blood thinning medicines) e.g. warfarin. Tramadol 50 mg Capsules could alter their effects if taken at the same time.

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 fits may increase if you take Tramadol 50 mg Capsules at the same time. Your doctor will tell you whether Tramadol 50 mg Capsules is suitable for you.
- If you are taking certain antidepressants. Tramadol 50 mg 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.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines including medicines obtained without prescription and herbal remedies.

Taking Tramadol 50 mg Capsules with food and drink

You should avoid alcohol during treatment with Tramadol 50 mg Capsules. If you use alcohol with Tramadol 50 mg Capsules you may feel drowsier than when you are taking alcohol alone.

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 if you are pregnant.

Chronic use during pregnancy may lead to withdrawal symptoms in newborns. Generally, the use of Tramadol is not recommended during breast-feeding. Small amounts of Tramadol are excreted into breast milk. After a single dose it is usually not necessary to interrupt breast-feeding. Based on human experience Tramadol is suggested not to influence female or male fertility.

Driving and using machines

Tramadol Capsules may cause drowsiness, dizziness and 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. 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.

3. HOW TO TAKE TRAMADOL 50 mg CAPSULES

Follow your doctor's instructions on how many Tramadol 50 mg Capsules to take and when to take them. You will also find this information on the label.

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.

You should usually swallow one or two capsules at a time. Do not take them more often than every four hours and do not take more than eight capsules in any 24 hours unless your doctor tells you to. Swallow the capsules whole, not divided or chewed, with sufficient liquid. Tramadol capsules do not need to be taken with food. If you are not sure, ask your doctor or pharmacist.

Do not take a different amount of Tramadol 50 mg Capsules or take it more often than your doctor has told you to. These Tramadol 50 mg Capsules are for you. You must not give them to other people.

If you have chronic pain (pain that lasts for long periods of time) it is best to take Tramadol 50 mg Capsules over short periods and only when you need it.

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 50 mg Capsules. If in your case the insufficiency is mild or moderate, your doctor may recommend prolonging the dosage interval.

If you take more Tramadol 50 mg Capsules than you should:-

If you take two single doses of Tramadol 50 mg capsules at once by mistake, this will generally not be harmful. If pain returns, continue taking Tramadol 50 mg Capsules as usual.

If high doses are taken accidentally (e.g. a dose of more than two Tramadol 50 mg Capsules at once), a number of symptoms may occur. These might include:- pin-point pupils, vomiting, a fall in blood pressure, a fast heartbeat, collapse, disturbed consciousness including coma (deep unconsciousness), epileptic fits and difficulties in breathing. If you suspect that you or someone else has taken an overdose of Tramadol 50 mg Capsules, contact your doctor or go to your local hospital immediately. Always take the carton and this leaflet with you if possible.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

If you forget to take Tramadol 50 mg Capsules

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

If you stop taking Tramadol 50 mg Capsules

Tramadol 50 mg Capsules may cause dependence (addiction / reliance on a medicine). Although this is rare, when you stop taking Tramadol 50 mg Capsules, you may feel agitated, anxious, nervous or shaky. You may

become hyperactive and have difficulty sleeping. Very few people may experience unusual effects on the nervous system such as confusion, delusions or unusual perceptions such as itching, tingling or numbness or noise in the ear (tinnitus) or stomach and bowel disorders. These effects usually disappear after a few days. Tell your doctor if you experience any of these symptoms after stopping Tramadol 50 mg Capsules.

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 are nausea and dizziness, which occur in more than 1 in 10 people.

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
- fatigue
- constipation, dry mouth, being sick (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, 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

- allergic reactions (e.g. difficulty in breathing, wheezing, swelling of skin) and shock (sudden circulation failure) have occurred in very rare cases
- 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), 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, confusional state, sleep disorders, delirium, 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), 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, breathing may slow down
- weak muscles passing urine with difficulty or pain, passing less urine than normal (dysuria).

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

- hepatic enzyme increased.

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, pharmacist or nurse. This includes any possible side

effects not listed in this leaflet. You can also report side effects directly to

United Kingdom

Yellow Card Scheme website: '<http://www.mhra.gov.uk/yellowcard>'

Ireland

HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2, Tell: +353 1 6764971, Fax: +353 1 6762517, website: www.hpra.ie, E-mail: '<mailto:medsafety@hpra.ie>'

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

5. HOW TO STORE TRAMADOL 50 mg CAPSULES

Keep out of the sight and reach of children.

Do not use Tramadol 50 mg Capsules 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 30°C.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Tramadol 50 mg Capsules contain

The active substance is called tramadol hydrochloride. Each Capsule contains 50 mg of tramadol hydrochloride. The other ingredients are Calcium hydrogen phosphate (dihydrate), Magnesium Stearate and Silica (Colloidal anhydrous). The capsule is made of gelatine and contains the colour Titanium dioxide (E171). The printing ink contains the ingredients shellac, Black Iron oxide, Soya Lecithin and Antifoam DC 1510.

What Tramadol 50 mg Capsules look like and the contents of the pack

Tramadol 50 mg Capsules are all white and have 'TR50' printed on the outside. They are packed in blister strips and supplied in boxes of 30 or 100 capsules.

Marketing Authorisation Holder and Manufacturer:

Relonchem Limited, Cheshire House, Gorsey lane, Widnes, Cheshire, WA8 0RP, UK.

Date leaflet last revised in: April 2017.