

**Package leaflet:
Information for the user**

Tramadol 50 mg capsules, hard

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
6. Contents of the pack and other information

1. What Tramadol is and what it is used for

Tramadol hydrochloride - 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 is used for the treatment of moderate to severe pain.

Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

2. What you need to know before you take Tramadol

Do not take Tramadol

- if you are allergic to active substance 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 have taken in the last two weeks, certain medicines called “monoamine oxidase inhibitors” or MAOIs (used to treat e.g. depression).
- if you have epilepsy that is not controlled with your current medicine;
- as a substitute in drug withdrawal.

Warnings and precautions

Talk to your doctor or pharmacist before taking Tramadol

- if you suffer from epilepsy or seizures (fits) or have had them in the past because tramadol could increase the risk of you having further fits
- if you have liver or kidney problems.
- Suffer from depression and you are taking antidepressants as some of them may interact with tramadol (see ‘Other medicines and Tramadol’)
- if you or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs (“addiction”).
- if you are a smoker.
- if you have ever had problems with your mood (depression, anxiety or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

This medicine contains tapentadol which is an opioid medicine. Repeated use of opioid painkillers may result in the drug being less effective (you become accustomed to it). It may also lead to dependence and abuse which may result in life-threatening overdose. If you have concern that you may become dependent on Tramadol, it is important that you consult your doctor. Use (even at therapeutic doses) may lead to physical dependence, which may result in you suffering withdrawal effects and a recurrence of your problems if you suddenly stop taking this medicine treatment.

- There is a small risk that you may experience a so-called serotonin syndrome that can occur after having taken tramadol in combination with certain antidepressants or tramadol alone. Seek medical advice immediately if you have any of the symptoms related to this serious syndrome (see section 4 ‘Possible side effects’).

As with all painkillers of this type (opioid analgesics), tramadol should be used with caution, and only under medical supervision in seriously ill patients including those with breathing difficulties, excessively low blood pressure (shock), decreased consciousness, serious head injury or brain diseases that may cause elevated pressure in the skull.

As with all medicines of this type, tramadol may lead to psychological and physical dependence or addiction in some people, especially with long term use. The dose needed to achieve the desired effect may increase with time. Tramadol should be used with caution, and only for short periods, in patients who are addicted to other opioid pain-killers.

Tramadol is transformed in the liver by an enzyme. Some people have a variation of this enzyme and this can affect people in different ways. In some people, they may not get enough pain relief but other people are more likely to get serious side effects. If you notice any of the following side effects, you must stop taking this medicine and seek immediate

medical advice: slow or shallow breathing, confusion, sleepiness, small pupils, feeling or being sick, constipation, lack of appetite.

Sleep-related breathing disorders

Tramadol can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

Talk to your doctor or pharmacist if you experience any of the following symptoms while taking Tramadol.

Extreme fatigue, lack of appetite, severe abdominal pain, nausea, vomiting or low blood pressure. This may indicate that you have adrenal insufficiency (low cortisol levels). If you have these symptoms, contact your doctor, who will decide if you need to take hormone supplement.

Children and adolescents

Use in children with breathing problems
Tramadol is not recommended in children with breathing problems, since the symptoms of tramadol toxicity may be worse in these children.

Other medicines and Tramadol

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

- Gabapentin or pregabalin to treat epilepsy and pain due to nerve problems (neuropathicpain)

Do not take Tramadol at the same time as medicines called “monoamine oxidase inhibitors” or MAOIs (which are used to treat e.g. depression), or if you have taken MAOIs in the past 2 weeks.

The pain-relieving effect of Tramadol may be weakened and/or shortened if you also take medicines containing:

- carbamazepine (used to treat epilepsy)
- ondansetron (used to stop you feeling sick).

The risk of side effects increases if you take Tramadol at the same time as:

- 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 serotonin syndrome (see section 4 ‘Possible side effects’).
- sedative medicines such as tranquilizers, sleeping pills, antidepressants and other pain relievers (morphine, codeine); you may feel excessively drowsy or feel that you might faint
- medicines that prevent blood clotting, such as warfarin; the dose of these medicines may need to be reduced, otherwise there could be an increased risk of potentially serious bleeding.

Concomitant use of Tramadol and sedative medicines such as benzodiazepines or related drugs increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However if your doctor does prescribe Tramadol together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all sedative medicines you are taking, and follow your doctor’s dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Tramadol with food and drink and alcohol

You should not drink alcohol during treatment with Tramadol, as its effect may be intensified.

Pregnancy and breast-feeding

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.

Pregnancy

There is very little information regarding the safety of tramadol during pregnancy. Tramadol should therefore not be used during pregnancy. If you become pregnant you should inform your doctor as soon as possible.

Breast-feeding

Tramadol is excreted into breast milk. For this reason, you should not take Tramadol more than once during breast-feeding, or alternatively, if you take Tramadol more than once, you should stop breast-feeding.

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

Driving and using machines

Tramadol may cause side effects such as sleepiness and dizziness. If this happens, do not drive or operate machinery.

Tramadol contains Sodium:

Tramadol capsules 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 or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

N04313

■ Black

Version: 11

Date & Time: 19.01.2024 & 3:50 pm

Submission: N04313_u15c

The capsules should be swallowed whole with a glass of water.

The capsules can be taken with or without food and should not be chewed.

The usual doses are given below. Your doctor may gradually increase or decrease your dose depending on how you respond to the treatment.

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.

Adults and adolescents aged 12 and over
The usual dose is 50 mg or 100 mg (1 or 2 capsules) every 4-6 hours, according to severity of pain. You should normally not take more than 400 mg (8 capsules) a day.

Children below 12 years of age
Tramadol is not recommended for use in children below age 12.

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.

If you take more Tramadol than you should

If you have taken more capsules than you have been told to take, contact your doctor immediately or go to your nearest hospital casualty department. A number of symptoms may occur, which might include: vomiting (being sick), a fall in blood pressure, a fast heartbeat, collapse, fainting or even coma, epileptic fits and difficulties in breathing.

If you forget to take Tramadol

If you forget to take Tramadol take it as soon as you remember and then carry on as before.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Tramadol

If you stop taking Tramadol, your pain may return.

You should not suddenly stop taking this medicine unless your doctor tells you to. If you want to stop taking your medicine, discuss this with your doctor first, particularly if you have been taking it for a long time. Your doctor will advise you when and how to stop, which may be by lowering the dose gradually to reduce the chance of developing unnecessary side effects (withdrawal symptoms).

If you would like to stop treatment because you have unpleasant side effects, please talk to your doctor. If you have been taking this medicine for a very long time, you may get the following side effects if you suddenly stop treatment: restlessness, anxiety, nervousness, shaking or an upset stomach. If you get any of these effects after stopping treatment with Tramadol please talk to 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.

Tramadol can occasionally cause allergic reactions although serious allergic reactions (including anaphylaxis and angioedema) are rare. Contact a doctor or emergency unit immediately if you experience any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body). The same applies in case of seizures ("fits").

The frequency of side effects is classified as follows:

Common:	may affect up to 1 in 10 people
Uncommon:	may affect up to 1 in 100 people
Rare:	may affect up to 1 in 1,000 people
Very rare:	may affect up to 1 in 10,000 people
Not known:	frequency cannot be estimated from the available data

The following side effects may occur:

Very common: nausea; dizziness.

Common: headache, sleepiness; vomiting (being sick), constipation, dry mouth; sweating.

Uncommon: Irregular, rapid beating or pulsation of the heart, increased heartbeat, low blood pressure (especially when standing upright), this may lead to collapse. These adverse effects may particularly occur in patients in an upright position or under physical strain. Diarrhoea, retching, gastrointestinal irritation (a feeling of pressure in the stomach, bloating); skin disorders (e.g. itchiness, rash, sudden onset of skin redness).

Rare: Slow heartbeat, rise in blood pressure; change in appetite, tingling skin sensation (e.g. pins and needles); trembling, breathing difficulties, epileptic-like seizures ("fits"), uncoordinated movement, muscle twitches, fainting; blurred

vision, dilation of pupils (mydriasis), constriction of pupils (miosis); difficulty in passing urine and urinary retention. Muscle weakness. Generalized allergic reactions (e.g. anaphylaxis and angioedema, see below). Hallucinations, confusion, anxiety, sleep disturbance and nightmares, changes in mood (high or low spirits), changes in activity (slowing down but sometimes an increase in activity) and being less aware and less able to make decisions, which may lead to errors in judgement.

Not known: Increased levels of liver enzymes. Worsening of asthma has been reported, however it has not been established whether it was caused by tramadol. Speech disorders, decrease in blood sugar level, Hiccups, Serotonin syndrome, that can manifest as mental status changes (e.g. agitation, hallucinations, coma), and other effects, such as fever, increase in heart rate, unstable blood pressure, involuntary twitching, muscular rigidity, lack of coordination and/or gastrointestinal symptoms (e.g. nausea, vomiting, diarrhoea) (see section 2 'What you need to know before you take Tramadol').

During use of Tramadol, dependence, abuse and addiction may occur. When treatment is stopped, symptoms of withdrawal reactions may occur, such as agitation, anxiety, nervousness, sleeplessness, uncontrolled muscular action (hyperkinesia), tremor and gastrointestinal symptoms. Other symptoms that have very rarely been seen with tramadol discontinuation e.g., panic attacks, severe anxiety, hallucinations, tingling skin sensation, hearing sounds e.g. ringing or buzzing, without an external cause (tinnitus).

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. 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 carton, bottle after EXP. The expiry date refers to the last day of that month.

Store below 30°C.

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 are:

Capsule contents: Cellulose, microcrystalline, silica colloidal anhydrous, sodium starch glycolate (Type A), magnesium stearate.

Capsule shell: Gelatin, sodium lauryl sulphate, indigo carmine, iron oxide yellow (E172) and titanium dioxide (E171).

Printing ink: Shellac and black iron oxide (E172).

What Tramadol looks like and contents of the pack

Green /Yellow, size '4' hard gelatin capsules filled with white to off-white powder and imprinted with 'T' on green cap and '02' on yellow body with black ink.

PVC/PVDC/Aluminium foil blister: 10, 20, 30, 50, 60, 90, 100 and 500 Capsules
HDPE bottle pack with polypropylene closure: 30,200 and 500 Capsules

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Milpharm Limited
Ares Block
Odyssey Business Park
West End Road
Ruislip HA4 6QD
United Kingdom

Manufacturer

APL Swift Services (Malta) Limited
HF26, Hal Far Industrial Estate, Hal Far,
Birzebbugia, BBG 3000
Malta

or

Milpharm Limited
Ares Block
Odyssey Business Park
West End Road
Ruislip HA4 6QD
United Kingdom

This leaflet was last revised in 01/2024.