

twitches, fainting; blurred vision; 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 (frequency cannot be estimated from the available data): 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.

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRa Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. 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 ("EXP") which is stated on the carton and the label or foil. The expiry date refers to the last day of that month.

Store in the original packaging in order to protect from light.
Store below 25°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

Capsule content

The active substance is tramadol hydrochloride 50 mg
The other ingredients are: maize starch, pregelatinised; cellulose, microcrystalline; magnesium stearate.

Capsule shell

Gelatine, indigo carmine (E132), titanium dioxide (E171), yellow iron oxide (E172).

Printing ink (Opacode Monogramming Ink S-1-277002 Black): Shellac, iron oxide black (E172), propylene glycol, ammonium hydroxide.

What Tramadol looks like and contents of the pack

Tramadol are hard gelatine capsules with dark green cap and yellow body, marked "TK" on one side.

Pack sizes:

Blister: 10, 20, 30, 50 and 100 capsules.
Capsule container: 100, 200 and 250 capsules (hospital use only).

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

MA Holder:
Accord Healthcare Ireland Ltd,
Euro House, Euro Business Park, Little Island,
Cork T45 K857, Ireland
Manufacturer:
Accord UK Ltd., Whiddon Valley, Barnstaple,
North Devon, EX32 8NS, UK.
Balkanpharma-Dupnitsa AD, 3 Samokovsko
Shosse Str., 2600 Dupnitsa, Bulgaria.
Accord Healthcare Polska Sp. z o.o.,
Ul. Lutomiarska 50,95-200 Pabianice,
Poland.

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accord

Package leaflet: information for the user

Tramadol hydrochloride 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
- 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.

2 What you need to know before you take Tramadol

Do not take Tramadol

- if you are allergic to tramadol hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- if you are under the influence of alcohol or sedative drugs including sleeping pills, other pain-killers or tranquilliser medicines.
- 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, and the antibiotic linezolid). The combination could result in a serious, potentially life threatening interaction.
- 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.

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.

Prolonged and frequent use of pain relieving medicines, such as tramadol, can cause the development of more severe or more frequent headaches. If this happens, you should not increase your dose of the pain relieving medicine, but contact your doctor for advice.

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.

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.

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.

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, such as tranquilizers, sleeping pills, antidepressants and other pain relievers (morphine, codeine), 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.

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

- carbamazepine (used to treat epilepsy).
- pentazocine, nalbuphine or buprenorphine (pain killers).
- ondansetron (used to stop you feeling sick).

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 fit may increase if you take Tramadol at the same time. Your doctor will tell you whether Tramadol is suitable for you.
- 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.
- 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.

In isolated cases the side effect of SSRI antidepressants worsen when taken with tramadol and "serotonin syndrome" may develop, the symptoms of which include confusion, restlessness, diarrhoea, fever and sweating. If this happens, contact the doctor.

Discontinuation of treatment with SSRI antidepressants usually relieves the symptoms.

Tramadol with food, 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.

Driving and using machines

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

3 How to take Tramadol

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor if you are not sure.

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.

Use in 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 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 following side effects may occur:

Very common (may affect more than 1 in 10 people): nausea; dizziness.

Common (may affect up to 1 in 10 people): headache, sleepiness; vomiting (being sick), constipation, dry mouth; sweating.
Uncommon (may affect up to 1 in 100 people): Irregular, rapid beating or pulsation of the heart, increased heartbeat, low blood pressure (especially when standing upright), this may lead to collapse. Diarrhoea, retching, gastrointestinal irritation (a feeling of pressure in the stomach, bloating); skin disorders (e.g. itchiness, rash, sudden onset of skin redness).

Rare (may affect up to 1 in 1,000 people): Slow heartbeat, rise in blood pressure; sleepiness, change in appetite, tingling skin sensation (e.g. pins and needles); trembling, breathing difficulties, epileptic-like seizures ("fits"), uncoordinated movement, muscle