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

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).
- in acute poisoning with alcohol, sleeping pills, pain-relievers or other psychotropic medicines (medicines that affect mood and emotions).
- if you are taking MAO inhibitors (certain medicines used for treatment of depression) or have taken them in the last 14 days before treatment with Tramadol hydrochloride (see “Other medicines and Tramadol”
- if you are an epileptic 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
- if you suffer from depression and you are taking antidepressants as some of them may interact with tramadol (see "Other medicines and Tramadol".

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').

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 (400mg).

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.

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 abuse medicines or who are dependent on medicines, 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.

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.

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.

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 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).

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

The risk of side effects increases if you are taking:
- 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.
- Concomitant use of Tramadol and tranquillizers or sleeping pills (e.g. benzodiazepines) 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 tranquillizers, 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.
- 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.
- Coumarin anticoagulants (medicines for blood thinning), e.g. warfarin, together with Tramadol. The effect of these medicines on blood clotting may be affected and bleeding may occur.

- Certain antidepressants. Tramadol may interact with these medicines and you may experience serotonin syndrome (see section 4 “Possible side effects”).

In isolated cases the side effect of SSRI antidepressants worsen when taken with tramadol and “serotonin syndrome” may develop (see section 4 “Possible side effects”). 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. Food does not influence the effect of Tramadol.

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

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.

Pregnancy
There is very little information regarding the safety of tramadol during pregnancy. Tramadol should therefore not be used during pregnancy. Chronic use during pregnancy may lead to withdrawal symptoms in newborns. 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.

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 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.

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. Do not take more than 400mg tramadol hydrochloride daily, 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
One or two capsules (equivalent to 50mg-100mg tramadol hydrochloride). Depending on the pain, the effect lasts for about 4-8 hours. Your doctor may prescribe a different, more appropriate dosage of Tramadol if necessary.

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.

How long should you take Tramadol?
You should not take Tramadol 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 capsules and at what dose.

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

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

If you stop taking Tramadol
If you interrupt or finish treatment with Tramadol Capsules too soon, pain is likely to return. If you wish to stop treatment on account of unpleasant effects, please tell your doctor.

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).

Generally there will be no after-effects when treatment with Tramadol Capsules is stopped. However, on rare occasions, people who have been taking Tramadol Capsules 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 reality (derealisation) and delusion of persecution (paronia) have been seen very rarely. If you experience any of these complaints, after stopping Tramadol Capsules, 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.

The following side effects may occur:

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

Common (may affect up to 1 in 10 people):
headache, drowsiness; fatigue, vomiting (being sick), constipation, dry mouth; 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 rare cases, slow heart beat, 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 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 (slowing down but sometimes an increase in activity) 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. 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 (dysponea). 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. Muscle weakness, 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, 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").

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
Website: www.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
*G*elatine, 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.
Accord Healthcare Polska Sp. z o.o., Ul. Lutomierska 50, 95-200 Pabianice, Poland

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