

Tramadol HCl Capsule 50 mg, capsules

tramadol hydrochloride

what is tramadol hcl capsule 50 mg and what is it used for?

Tramadol HCl capsule 50 mg belongs to the group of medicines called opioid analgesics (morphine-like painkillers). It relieves pain by inhibiting certain parts of the central nervous system (the brain and spinal cord).

Tramadol HCl capsule 50 mg is used:for moderate to severe pain.

When should you not use this medicine or be extra careful with it?

When should you not take this medicine: if you are allergic to any of the ingredients in this medicine, in case of acute poisoning by alcohol, sleeping pills, painkillers or other psychotropic medicines (medicines that affect mood and emotions);, if you are also taking a monoamine oxidase inhibitor (MAO inhibitor) for severe depression or have taken one in the last 14 days (see "Are you taking any other medicines?");,if you have epilepsy and your seizures are not sufficiently controlled with medication;; as treatment for withdrawal symptoms in drug addicts.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before taking this medicine:

If you think you are addicted to other painkillers (opioids);• if you have consciousness disorders (feeling like you might faint);• if you are in a state of shock (cold sweat may be a sign of this);• if you have increased pressure in the brain (for example, due to head injury or brain disease);• if you have breathing problems;• if you have a tendency to epilepsy or seizures, as the risk of seizure may be increased;• if you have liver or kidney disease;• if you have depression and are taking antidepressants, as some of these medications may interact with tramadol (see "Are you taking any other medicines?").

There is a small risk of a condition called serotonin syndrome that may occur after using tramadol alone or in combination with certain antidepressants. Consult a doctor immediately if you experience any symptoms of this serious syndrome (see section 4 "Possible side effects").

Sleep-related breathing disorders: Tramadol HCl contains an active ingredient that belongs to the group of opioids. Opioids can cause sleep-related breathing disorders, such as central sleep apnea (shallow/breathing pauses during sleep) and sleep-related hypoxemia (low oxygen levels in the blood). The risk of central sleep apnea depends on the opioid dose. Possible symptoms include breathing pauses during sleep, waking up at night due to shortness of breath, difficulty staying asleep, or excessive daytime sleepiness. If you or someone else experiences these symptoms, contact your doctor. Your doctor may consider reducing the dose.

Seizures have been reported in patients taking tramadol at recommended doses. The risk may be increased when the upper limit of the recommended daily dose (400 mg) is exceeded.

Note: This medicine can lead to physical and psychological dependence. With prolonged use, the effect of this medicine may decrease, requiring higher doses (development of tolerance).

Patients who are inclined to misuse or are dependent on medications should only be treated with this medicine for short periods and under strict supervision.

Notify your doctor if any of these problems occur during treatment with this medicine or if you have had any of these problems in the past.

Tramadol is converted in the liver by an enzyme. Some people have a variation of this enzyme and this can affect them in different ways. In some people, pain relief may be inadequate, while in others, there may be more serious side effects. If you notice one or more of the following symptoms, stop taking the medication and immediately consult a doctor: slow or shallow breathing, confusion, drowsiness, narrowed pupils, nausea or vomiting, constipation, and loss of appetite.

Get in touch with your doctor if you experience the following symptoms while using Tramadol HCl Sandoz: extreme fatigue, loss 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. Your doctor will decide if you need to take hormone supplements.

Elderly patients over 75 years old should be carefully monitored because tramadol may be eliminated more slowly from the body (see section 3 "How to use this medicine?").

Use in children and adolescents under 18 years old: Tramadol is not recommended for children with respiratory problems, as the symptoms of tramadol poisoning in these children may be more severe.

Are you using any other medicines? If you are taking any other medicines with Tramadol HCl capsule 50 mg, have recently taken any other medicines, or may use other medicines in the near future, tell your doctor or pharmacist.

This medicine should not be used at the same time as MAO inhibitors (certain medicines for the treatment of depression).

The analgesic effect and duration of Tramadol HCl capsule 50 mg may decrease if you take medicines that contain: • carbamazepine (for epilepsy); • ondansetron (prevents nausea).

Your doctor will tell you if and in what dosage you can use this medicine.

The risk of side effects increases when you: • use this medicine at the same time as sedatives such as benzodiazepines or similar medicines, which increases the risk of drowsiness, breathing difficulties (respiratory depression), coma, and can be life-threatening. Therefore, concurrent use should only be considered when other treatment options are not possible. However, when your doctor still prescribes this medicine together with sedatives, the dose and duration of concurrent use should be limited by your doctor. Inform your doctor of all sedatives you are using and closely follow the recommendation your doctor gives you regarding the dosage. It may help to inform your friends or family about the signs and symptoms described above. Contact your doctor if you experience such symptoms. • use other medicines that also have a sedative effect on brain function. For example, other painkillers such as morphine and codeine (also as a cough medicine). The same applies to the use of alcohol. You may feel more drowsy or feel like fainting. If this happens, tell your doctor. • take medicines that can cause seizures, such as certain medicines for the treatment of depression or psychosis. The likelihood of having a seizure increases.

May increase if used at the same time. Your doctor will tell you if this medicine is suitable for you.

- Taking certain antidepressants. Tramadol HCl 50 mg capsule and these medicines can interact with each other and you may experience symptoms such as serotonin syndrome (see section 4 'Possible side effects').
- Using coumarin anticoagulants (blood thinners), such as warfarin, together with this medicine. The effect of these medicines on blood clotting may be affected and severe bleeding and small bleeding in the skin or mucous membranes (ecchymoses) may occur.
- Medicines containing ondansetron (anti-nausea medication used in chemotherapy, radiotherapy, and surgery). The need for tramadol may be increased.

What to watch for with food and alcohol?: Do not drink alcohol while using this medicine as it can enhance its effect. Food does not affect the functioning of this medicine.

Pregnancy, breastfeeding, and fertility: Are you pregnant, think you might be pregnant, want to become pregnant or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine.

Pregnancy: Very little is known about the safety of tramadol during pregnancy. Therefore, you should not use this medicine if you are pregnant. Chronic use during pregnancy can cause withdrawal symptoms in newborns.

Breastfeeding: Tramadol is excreted in breast milk. For this reason, you should not take this medicine more than once during the breastfeeding period. If you use this medicine more than once, you should stop breastfeeding.

Fertility: Based on human experience, tramadol hydrochloride does not appear to affect fertility in women or men.

Driving and using machines: This medicine may cause drowsiness, dizziness, and blurred vision, which may decrease your reaction time. If you think your reaction time has decreased, you should not drive a car or any other vehicle, use power tools or operate machinery.

This medicine contains less than 1 mmol of sodium (23 mg) per capsule, which means that it is essentially 'sodium-free'.

How to use this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct use, please contact your doctor or pharmacist.

The following doses generally apply: Adults and children over 12 years old: 3 to 4 times a day, take 1 to 2 capsules. If insufficient pain relief is achieved, your doctor will gradually increase the dose until adequate pain relief is achieved.

Maximum dosage: 8 capsules (400 mg) per day.

Elderly patients: In elderly patients (over 75 years old), the excretion of tramadol may be slowed down. If this applies to you, your doctor may advise you to increase the time interval between doses.

Children under 12 years old: Tramadol HCl capsule 50 mg should not be administered to children as the dose cannot be properly adjusted. Therefore, other forms of administration should be used.

Patients with severe liver and/or kidney disease (insufficiency)/dialysis patients: Patients with severe liver and/or kidney disease should not use tramadol. If there is mild or moderate insufficiency, your doctor may advise you to increase the time interval between doses.

Method of administration: Take the capsules whole with water, regardless of meals.

In case you notice that Tramadol HCl capsule 50mg is too strong or too weak, consult your doctor or pharmacist.

Duration of treatment: Your doctor will tell you how long you should use Tramadol HCl capsule 50mg. Do not stop treatment prematurely, as the symptoms may recur.

Did you use too much of this medicine?

If you have used too much Tramadol HCl capsule 50mg, contact your doctor or pharmacist immediately. Symptoms of overdose may include: pupil constriction (miosis), vomiting, severely low blood pressure, drowsiness and coma, seizures, and breathing difficulties.

Did you forget to take this medicine: If you forget to take a dose, you can still take it unless it is almost time for your next dose. In this case, follow the normal dosing schedule. Do not take a double dose to make up for a missed dose. If you stop using this medication, do not stop taking it suddenly unless your doctor tells you to. If you want to stop taking this medication, discuss it with your doctor first, especially if you have been

using it for a long time. Your doctor will tell you when and how you can stop, for example by gradually reducing the dose to reduce the risk of unnecessary side effects (withdrawal symptoms).

Possible side effects: Like any medicine, this medicine can have side effects, although not everyone gets them. Go to a doctor immediately if you have the following symptoms of an allergic reaction: swollen face, tongue and/or throat and/or swallowing problems or hives accompanied by breathing problems.

Very common (affects more than 1 in 10 users):• Dizziness,• Nausea

Common (affects less than 1 in 10 users): • Headache, drowsiness, • Fatigue,• Constipation, dry mouth, vomiting,• Sweating (hyperhidrosis)

Uncommon (affects less than 1 in 100 users):• Effects on the heart and circulation (palpitations, fast heartbeat, fainting or fainting spells). These side effects occur especially when the patient is standing upright or under physical stress.• Nausea, stomach complaints (such as pressure or bloated feeling in the stomach), diarrhea• Skin reactions (such as itching, rash)

How to store this medicine?

Store below 25°C. Store in the original packaging to protect against moisture and light.