

- 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. pins and needles), 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).
- 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):

- liver enzymes increased

Not known (frequency cannot be estimated from the available data):

- decrease in blood sugar level
- dependence and addiction (see section "How do I know if I am addicted?").

Drug Withdrawal

When you stop taking Tramadol capsules, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating. Other symptoms that may develop include; panic attacks, severe anxiety, hallucinations, pins and needles, ringing in the ears, confusion, delusion, change of perception of own personality (depersonalisation), change in perception of reality (derealisation) and paranoia.

How do I know if I am addicted?

If you notice any of the following signs whilst taking Tramadol capsules, it could be a sign that you have become addicted.

- You need to take the medicine for longer than advised by your prescriber
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than prescribed
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these signs, it is important you talk to your prescriber

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 the Yellow Card Scheme at: 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 capsules

Keep out of the sight and reach of children.
Do not store above 30°C.
Do not take Tramadol capsules after the expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month.
Do not throw away this medicine via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

6 Contents of the pack and other information

What Tramadol capsules contain

- The active substance is tramadol hydrochloride.
- The other ingredients are pregelatinised starch, microcrystalline cellulose (E460), magnesium stearate
- The capsule shell contains gelatin, iron oxide (E172), titanium dioxide (E171), indigo carmine (E132). The printing ink contains shellac glaze, iron oxide black (E172) and propylene glycol.

What Tramadol capsules look like and contents of the pack

Tramadol capsules are yellow and green, opaque, hard gelatin capsules (size 4) printed "TK" in black.
Pack sizes are 30 and 100.

Marketing Authorisation Holder and Manufacturer

Accord, Barnstaple, EX32 8NS, UK

Date of revision: February 2021

accord

Package leaflet: Information for the patient

Tramadol hydrochloride 50mg capsules

2 What you need to know before you take Tramadol capsules

Do not take Tramadol capsules:

- if you are allergic to tramadol hydrochloride, or any of the 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 also taking MAO inhibitors (certain medicines used for treatment of depression) or have taken them in the last 14 days before treatment with Tramadol capsules (see "Other medicines and Tramadol capsules").
- 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 capsules if you:

- suffer from consciousness disorders (if you feel that you are going to faint);
- are in a state of shock (cold sweat may be a sign of this);
- suffer from increased pressure in the brain (possibly after a head injury or brain disease);
- have difficulty in breathing;
- have a tendency towards epilepsy or fits because the risk of a fit may increase;
- suffer from a liver or kidney disease;
- are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- feel you need to take more Tramadol capsules to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative pain reliever.

Taking this medicine regularly, particularly for a long time, can lead to addiction. 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.

Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your prescriber about your treatment.

This medicine contains Tramadol hydrochloride which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in the leaflet. See section 4.

What is in this leaflet

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

1 What Tramadol capsules are and what they are used for

This medicine has been prescribed for you for the relief of moderate or severe pain.

It contains Tramadol hydrochloride which belongs to a class of medicines called opioids, which are 'pain relievers'. This medicine has been prescribed to you and should not be given to anyone else.

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, when it is appropriate to stop and how to do this safely.

Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms.

Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of opioid may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

Sleep-related breathing disorders

Tramadol capsules contain an active substance that belongs to the group of opioids. Opioids can cause sleep-related breathing disorders, for example central sleep apnoea (shallow/pause of breathing during sleep) and sleep-related hypoxemia (low level of oxygen in the blood).

The risk of experiencing central sleep apnoea is dependent on the dose of opioids. Your doctor may consider decreasing your total opioid dosage if you experience central sleep apnoea.

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 also inform your doctor if one of these problems occurs during Tramadol treatment or if they applied to you in the past.

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.

Other medicines and Tramadol capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any 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 may be reduced and the length of time it acts may be shortened, if you take medicines which contain

- carbamazepine (for epileptic fits);
- ondansetron (prevents nausea).

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

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 capsules. You may feel drowsier or feel that you might faint. If this happens, tell your doctor.

Concomitant use of Tramadol capsules and tranquilizers 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 prescribes Tramadol capsules together with sedating medicines the dose and the duration of concomitant treatment should be limited by your doctor. Please tell your doctor about all sedating 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

- 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 capsules at the same time. Your doctor will tell you whether Tramadol capsules are suitable for you.
- if you are taking certain antidepressants, Tramadol 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 .
- if you are taking coumarin anticoagulants (medicines for blood thinning), e.g. warfarin, together with Tramadol capsules. The effect of these medicines on blood clotting may be affected and bleeding may occur.

Tramadol capsules with food and alcohol

Do not drink alcohol during treatment with Tramadol capsules as the effect may be intensified.

Food does not influence the effect of Tramadol capsules.

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

Do not take Tramadol capsules if you are pregnant or think you might be pregnant unless you have discussed this with your prescriber and the benefits of treatment are considered to outweigh the potential harm to the baby.

If you use Tramadol capsules during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Do not take Tramadol capsules while you are breastfeeding as Tramadol passes into breast milk and will affect your baby.

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

Driving and using machines

Tramadol capsules may make you feel drowsy, dizzy or in rare cases blur your vision. This may be made worse if you drink alcohol or take other medicines such as strong painkillers with tramadol. Make sure you are not affected before you drive or operate machinery.

The medicine can affect your ability to drive as you may feel 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 capsules

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

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 400 mg 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 Tramadol capsules (equivalent to 50 mg – 100 mg 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.

Children

Tramadol 50 mg Capsules are not suitable for children below the age of 12 years.

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

How and when should you take Tramadol capsules?

Tramadol capsules are for oral use.

Always swallow Tramadol capsules whole, not divided or chewed, with sufficient liquid, preferably in the morning and evening. You may take the capsule on an empty stomach or with meals.

How long should you take Tramadol Capsules

Your prescriber should have discussed with you how long the course of Tramadol capsules will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.

You should not take Tramadol Capsules 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 have the impression that the effect of Tramadol Capsules is too strong or too weak, talk to your doctor or pharmacist.

If you take more Tramadol Capsules 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 Capsules

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

If you stop taking Tramadol Capsules

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

Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine. Also see under section 4 "**Drug Withdrawal**". If you experience any of these complaints after stopping Tramadol, 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.

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), 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.