

Tramadol 50 mg Capsules

Package leaflet: Information for the user

This medicine contains Tramadol 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 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 of the 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

- This medicine has been prescribed for you to relieve or to prevent moderate to severe pain. It contains Tramadol 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 and when it is appropriate to stop, and how to do this safely.

2 What you need to know before you take Tramadol

Do not take Tramadol:

- if you are allergic to Tramadol or any of the other ingredients of this medicine
- if you have taken enough alcohol to make you feel even slightly drunk
- if you have taken several sleeping pills, other pain killers, psychotropic medicine (medicines that affects mood and emotion)
- 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 taking other medicines)
- 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 prescriber before taking this medicine if you:

- 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 of Tramadol 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.

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.

Tell your doctor if you:

- have or recently had a head injury or brain disease and due to that you are suffering from increased pressure in the brain
- have had any problems with your kidneys or liver
- suffer from epilepsy, fits or seizures or have had them in the past. In such cases please consult your doctor before taking the medicine. 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).
- suffer from asthma or other lung diseases, or have slow or troubled breathing
- 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).

When Tramadol is taken for a long time, its effect may decrease, so that higher doses have to be taken (tolerance development).

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, especially:

- other medicines that slow the nervous system, including tranquillisers, sleeping pills, antidepressants and other pain relievers such as morphine and codeine
- lithium (a medicine used to treat certain types of mental illness)
- cimetidine (a medicine used to treat certain conditions caused by too much acid being produced in the stomach)
- medicines which may cause convulsions (fits), such as certain antidepressants. The risk of having a fit may increase if you take Tramadol at the same time.
- selective serotonin reuptake inhibitors (often referred to as SSRIs, used to treat depression). Tramadol may interact with these medicines and you may experience symptoms such as confusion, restlessness, fever, sweating, uncoordinated movement of limbs or eyes, uncontrollable jerking of muscles, or diarrhoea.
- if you take 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.

Before you have general anaesthetics (medicines used for temporary loss of bodily sensation during an operation) make sure you tell your doctor or dentist that you are taking Tramadol Capsules.

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.

Do not take Tramadol if you are taking:

- a monoamine oxidase inhibitor (MAOI, which is a type of medicine that can treat Parkinson's Disease or depression) such as selegiline or moclobemide, or if you have taken any of these medicines within the past two weeks.

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)
- pentazocine, nalbuphine or buprenorphine (pain killers)
- ondansetron (prevents nausea).

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.
- if you are taking 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.

Tramadol with food and drink

DO NOT take alcohol whilst taking Tramadol capsules. Food does not influence the effect of Tramadol.

Pregnancy and breast-feeding

Do not take Tramadol 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 during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

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

Driving and using machines

Tramadol may cause drowsiness, dizziness and blurred vision. This may be made worse if alcohol and/or other medicines that slow the nervous system such as phenobarbital, diazepam, amitriptyline, chlorpromazine are taken at the same time. If you are affected, DO NOT drive or operate machinery.

The medicine can affect your ability to drive as it may make you 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.

Tramadol contains Sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3 How to take Tramadol

Tramadol Capsules are for oral use. Always swallow Tramadol whole, not divided or chewed, with sufficient liquid.

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

Your prescriber should have discussed with you, how long the course of 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.

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.

The capsules should be swallowed preferably with a drink of water. The recommended dose is:

- **Adults, Elderly and Children aged 12 years and over**

1 or 2 capsules every four hours.

Do not take more than 8 capsules in 24 hours.

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.

- **Children aged under 12 years**

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

- **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 and at what dose. If you have the impression that the effect of Tramadol is too strong or too weak, talk to your doctor or pharmacist.

If you take more Tramadol than you should

If you (or someone else) swallow too many capsules all together, or if you think a child has swallowed any of the capsules, contact your nearest hospital casualty department or your doctor immediately.

An overdose is likely to cause contraction of the pupils of the eyes, vomiting, loss of effective blood flow, sedation and coma, fits and difficulties in breathing.

Please take this leaflet, any remaining capsules and the container with you to the hospital or doctor so that they know which capsules were consumed.

If you forget to take Tramadol

If you forget to take this medicine, take one as soon as you remember, unless it is nearly time to take the next one. Do not take a double dose to make up for a forgotten dose.

If you stop taking Tramadol

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.

Very few people may get panic attacks, delusions, paranoia, hallucinations or feeling a loss of identity. They may experience unusual perceptions such as itching, tingling and numbness, and "ringing" in the ears (tinnitus). 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.

Stop taking the capsules and tell your doctor immediately or go to the casualty department at your nearest hospital if the following happens:

- an allergic reaction causing swelling of the lips, face or neck leading to severe difficulty in breathing, or severe skin rash or hives
- shock/ sudden circulation failure
- difficulty breathing
- a fit
- a constant sore throat or high temperature.

These are very serious but rare side effects. You may need urgent medical attention or hospitalisation.

Other possible side effects

Very common: may affect more than 1 in 10 people

- dizziness
- feeling sick.

Common: may affect up to 1 in 10 people

- headaches, drowsiness
- being sick, constipation, dry mouth
- sweating
- tiredness, weakness, low energy.

Uncommon: may affect up to 1 in 100 people

- effects on the heart and blood circulation (pounding of the heart, fast heart beat, a fall in blood pressure on standing up which causes dizziness, light-headedness, 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

- slow heart beat, increase in blood pressure
- changes in appetite, abnormal sensations (e.g. itching, tingling, numbness), trembling, slow breathing, epileptic fits, muscle twitches, uncoordinated movement, transient loss of consciousness (syncope)
- hallucinations, confusion, sleep disorders, anxiety and nightmares
- blurred vision
- shortness of breath (dyspnoea)
- weak muscles
- passing water difficult or painful, less urine than normal.

Very rare: may affect up to 1 in 10,000 people

- increase in liver enzyme values.

Not known: frequency cannot be estimated from the available data

- difficulty in speaking
- decrease in blood sugar level
- dilation of the pupil
- dependence and addiction (see section "How do I know if I am addicted?").

If the recommended doses are exceeded, or if other medicines that depress brain function are taken at the same time, breathing may slow down. 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.

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 being less aware and less able to make decisions, which may lead to errors in judgement. Dependence may occur.

Worsening of asthma has been reported, however it has not been established whether it was caused by tramadol.

Excessive sweating has been reported during the treatment with Tramadol, although the frequency is not known.

Feeling flushed (feeling hot and red skin) has rarely been seen during the treatment. Blood disorders have been reported. Blood disorders may be characterised by fever or chills, sore throat, ulcers in your mouth or throat, unusual tiredness or weakness, unusual bleeding or unexplained bruising.

Drug Withdrawal

When you stop taking Tramadol, 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.

How do I know if I am addicted?

If you notice any of the following signs whilst taking Tramadol, 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 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 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

Keep this medicine out of the sight and reach of children.

Keep this medicine in a dry place below 30°C.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not throw away any medicine 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 Capsules contain:

- The active ingredient is Tramadol Hydrochloride 50 mg.
- The other ingredients are microcrystalline cellulose, sodium starch glycolate, magnesium stearate, colloidal anhydrous silica.
- The capsule shell contains gelatin, indigo carmine E132, iron oxide yellow E172, titanium dioxide E171, shellac, iron oxide black E172 and propylene glycol E1520.

What Tramadol Capsules look like and contents of the pack:

- Tramadol 50 mg Capsules are green and pale yellow capsules marked with 9T1 50.
 - Tramadol 50 mg Capsules are available in pack sizes of 10, 20, 30, and 100 capsules.
- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation holder and company responsible for manufacture: TEVA UK Limited, Eastbourne, BN22 9AG.

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