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# TRAMADOL

## 50 mg 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 50 mg Capsules contain the active substance tramadol hydrochloride, which belongs to a group of medicines called opioid analgesics. 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, how to do this safely.

These act on specific nerve cells of the spinal cord and brain. Tramadol is used to relieve moderate to severe pain.

### 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TRAMADOL

**Do not take Tramadol and tell your doctor 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);
- have taken medicines known as monoamine oxidase inhibitors (MAOIs) to treat depression within the last 14 days (see 'Other medicines and Tramadol')
- suffer from epilepsy and your fits are not well controlled by treatment
- as a substitute in drug withdrawal

#### Warnings and precautions

Talk to your doctor before taking Tramadol 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;
- 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 fit because the risk of a fit may increase;
- suffer from depression and you are taking antidepressants as some of them may interact with tramadol (see 'Other medicines and Tramadol').
- suffer from a liver or kidney disease

#### Hyperalgesia

Hyperalgesia may be diagnosed if the patient on long-term opioid therapy presents with increased pain.

This might be qualitatively and anatomically distinct from pain related to disease progression or to breakthrough pain resulting from development of opioid tolerance. Pain associated with hyperalgesia tends to be more diffuse than the pre-existing pain and less defined in quality. Symptoms of hyperalgesia may resolve with a reduction of opioid dose.

#### Sleep-related breathing disorders

Tramadol contains 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 oxygen level in the blood).

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

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 (400 mg).

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.

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.

#### Tolerance, dependence, and addiction

This medicine contains tramadol which is an opioid medicine. Repeated use of opioids can result in the drug being less effective (you become accustomed to it, known as tolerance).

Repeated use of tramadol can also lead to dependence, abuse and addiction, which may result in life-threatening overdose. The risk of these side effects can increase with a higher dose and longer duration of use.

Dependence or addiction can make you feel that you are no longer in control of how much medicine you need to take or how often you need to take it. The risk of becoming dependent or addicted varies from person to person. You

may have a greater risk of becoming dependent on or addicted to Tramadol if:

- You or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ("addiction").
- You are a smoker.
- You have ever had problems with your mood (depression, anxiety, or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.



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

- You need to take the medicine for longer than advised by your doctor
- You need to take more than the recommended dose
- You are using the medicine for reasons other than prescribed, for instance, 'to stay calm' or 'help you sleep'
- You have made repeated, unsuccessful attempts to quit or control the use of the medicine
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again ('withdrawal effects')

If you notice any of these signs, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to stop safely (See section 3, If you stop taking Tramadol).

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

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.

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 medical advice: slow or shallow breathing, confusion, sleepiness, small pupils, feeling or being sick, constipation or lack of appetite.

#### Other medicines and Tramadol

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines, including medicines bought without a prescription. This is because Tramadol can affect the way some medicines work, and some medicines can affect the way Tramadol works.

Gabapentin or pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain)  
Tramadol 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 (used to treat epileptic fits)
- ondansetron (prevents nausea)

Your doctor will advise you whether you should take tramadol, and what dose.

#### The risk of side effects increases,

- if you take 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 tranquilizers, sleeping pills (e.g. benzodiazepines) or other sedatives or medicines that impair breathing activity (e.g. opioids) or gabapentin or pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain) increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma or 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 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. On concurrent use of tramadol, the risk of having a fit may increase. 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 serotonin syndrome (see section 4 'Possible side effects').
- if you are taking 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.
- medicines used to treat allergies, travel sickness or nausea (antihistamines or antiemetics).
- medicines to treat psychiatric disorders (antipsychotics or neuroleptics).
- muscle relaxants.
- medicines to treat Parkinson's disease.

#### Tramadol with food and alcohol

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

Tramadol tablets can be taken with or without food.

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

Administration during labour may depress respiration in the neonate and an antidote for the child should be readily available.

#### Driving and using machines

Tramadol may cause drowsiness, dizziness and blurred vision and therefore impair your reactions. If you feel that your reactions are affected, do not drive a car or do not use electric tools 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:
  - Tramadol 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 capsule, that is to say essentially 'sodium-free'.

### 3. HOW TO TAKE TRAMADOL

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

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using Tramadol, when and how long you need to take it, when to contact your doctor, and when you need to stop it (see also section 2).

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 recommended dose is:**

#### Adults and children aged 12 years and over:

One or two Tramadol (equivalent to 50 mg - 100 mg Tramadol) 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 below the age of 12 years:

Tramadol 50 mg Capsules are not suitable for use in children under 12 years of age.

#### Elderly patients (above 75 years):

In elderly patients the excretion of tramadol may be delayed. If this applies to you, your doctor may recommend prolonging the dosage interval accordingly.

#### Severe liver or kidney disease (including 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 and when should you take Tramadol?

Tramadol are for oral use.

Always swallow Tramadol 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?

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.

#### 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 at the same time you should go to hospital or call a doctor straight away. Signs of a overdose include very small pupils, being sick, vomiting, fall in blood pressure, a fast heartbeat, collapse, disturbed consciousness up to coma (deep unconsciousness), epileptic fits and breathing difficulties or shallow breathing

#### If you forget to take Tramadol

If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose and take your next scheduled dose at the correct time. Do not take a double dose to make up for a forgotten dose, and remember to allow at least four hours between doses.

#### If you stop taking Tramadol

Do not stop taking Tramadol suddenly. If you want to stop taking Tramadol you should discuss this with your doctor first. They will tell you when and how to do this, usually by reducing dose gradually so that any unpleasant withdrawal symptoms 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.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

### 4. POSSIBLE SIDE EFFECTS

Like all medicines, Tramadol 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 most common side effects during treatment with Tramadol are nausea and dizziness, which occur in more than 1 in 10 people.

#### Very common (may affect more than 1 in 10 people):

- dizziness
- feeling sick (nausea)

#### Common (may affect up to 1 in 10 people):

- headache, drowsiness
- being sick (vomiting), constipation, dry mouth
- sweating (hyperhidrosis)
- fatigue

#### 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 sick (retching), stomach trouble (a 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.
- increased blood pressure,
- slow heart beat
- abnormal sensations (e.g. itching, tingling, numbness), epileptic fits, trembling, muscle twitches, uncoordinated movement, transient loss of consciousness (syncope), speech disorders.
- epileptic fits, these may occur when high doses of Tramadol are being taken, or when Tramadol was taken at the same time as other medicines which may induce fits.
- changes in appetite
- hallucinations, 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 pupils (mydriasis), constriction of pupils (miosis)
- slow breathing, shortness of breath (dyspnoea)
- worsening of asthma (breathing difficulties) 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)

- hepatic enzyme increased

#### Not known: frequency cannot be estimated from the available data

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

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').

#### 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 Yellow Card Scheme: [www.mhra.gov.uk/yellowcard](http://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 out of the sight and reach of children.

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

Do not store above 25°C. Store in the original package. Keep the container tightly closed.

Store this medicine in a safe and secure storage space, where other people cannot access it. It can cause serious harm and be fatal to people when it has not been prescribed for them.

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 Capsules contain

The active substance, (the ingredient which makes the medicine work), is tramadol hydrochloride. Each capsule contains 50 mg of tramadol hydrochloride. The other ingredients are:

- capsule powder: colloidal anhydrous silica, magnesium stearate, microcrystalline cellulose (E460) and sodium starch glycolate (Type A)
- capsule shell: gelatine, titanium dioxide (E171), yellow iron oxide (E172)

#### What Tramadol Capsules look like and contents of the pack

Tramadol Capsules are opaque, yellow and yellow hard gelatine capsules. The size of capsule is about 14.4 mm. The capsules are available in blister packs and containers of 10, 20, 30, 50 and 100 capsules. Not all pack sizes may be marketed.

#### Marketing Authorisation Holder

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For any further information about this medicine, please contact the Marketing Authorisation Holder.

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