Package leaflet: Information for the user

Tramadol Hydrochloride 50 mg Capsules

<u>This medicine contains tramadol which is an opioid, which can cause addiction.</u>
<u>You can get withdrawal symptoms if you stop taking it suddenly.</u>

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 Hydrochloride is and what it is used for
2. What you need to know before you take Tramadol Hydrochloride
3. How to take Tramadol Hydrochloride
4. Possible side effects
5. How to store Tramadol Hydrochloride
6. Contents of the pack and other information

1. What Tramadol Hydrochloride is and what it is used for

The full name of your medicine is 'Tramadol Hydrochloride 50mg capsules'. It is referred to as 'Tramadol Hydrochloride' in the rest of this leaflet.

This medicine has been prescribed for you for the treatment of moderate to severe pain.

Tramadol - the active substance in Tramadol Hydrochloride 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, how to do this safely.

2. What you need to know before you take Tramadol Hydrochloride

Do not take Tramadol Hydrochloride,
- if you are allergic to tramadol 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 also 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 Hydrochloride");
- 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 before taking Tramadol Hydrochloride if:

- you suffer from consciousness disorders (if you feel that you are going to faint);
- you are in a state of shock (cold sweat may be a sign of this);
- you suffer from increased pressure in the brain (possibly after a head injury or brain disease);
- you have difficulty in breathing;
- you have a tendency towards epilepsy or fits because the risk of a fit may increase;
- you suffer from depression and you are taking antidepressants as some of them may interact with tramadol (see "Other medicines and Tramadol Hydrochloride");
- you suffer from a liver or kidney disease;

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 Hydrochloride 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 Hydrochloride 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 Hydrochloride, 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 Hydrochloride).

Sleep-related breathing disorders
Tramadol Hydrochloride contains an active substance that belongs to the group of opioids. Opioids can cause sleep-related breathing disorders, for example central sleep apnea (shallow/pause of breathing during sleep) and sleep-related hypoxemia (low level of oxygen 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.

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

Talk to your doctor if you experience any of the following symptoms while taking Tramadol Hydrochloride:
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 Hydrochloride
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
– Gabapentin or pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain)

Tramadol Hydrochloride should not be taken together with MAO inhibitors (certain medicines for the treatment of depression).

The pain-relieving effect of Tramadol Hydrochloride 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 Hydrochloride, 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 Hydrochloride. You may feel drowsier or feel that you might faint. If this happens tell your doctor.
– Concomitant use of Tramadol Hydrochloride and tranquillizers, 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 Hydrochloride 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

- medicines which may cause convulsions (fits), such as certain antidepressants or antipsychotics. The risk having a fit may increase if you take Tramadol Hydrochloride at the same time. Your doctor will tell you whether Tramadol Hydrochloride is suitable for you.
- certain antidepressants Tramadol Hydrochloride may interact with these medicines and you may experience serotonin syndrome (see section 4 "Possible side effects").
- coumarin anticoagulants (medicines for blood thinning), e.g. warfarin, together with Tramadol Hydrochloride. 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 Hydrochloride with food and alcohol
Do not drink alcohol during treatment with Tramadol Hydrochloride as its effect may be intensified.

Food does not influence the effect of Tramadol Hydrochloride.

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 Hydrochloride 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 Hydrochloride during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Do not take Tramadol Hydrochloride 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 Hydrochloride 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.

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.

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

3. How to take Tramadol Hydrochloride

Always take this medicine exactly 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 Hydrochloride, 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 usual dose is:

Adults and adolescents from the age of 12 years
One or two Tramadol Hydrochloride (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 Hydrochloride if necessary.

Children
Tramadol Hydrochloride 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 Hydrochloride. 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 hydrochloride?
Tramadol Hydrochloride are for oral use.
Always swallow Tramadol Hydrochloride 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 Hydrochloride?
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 Hydrochloride 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.

After taking very high doses, pin-point pupils, vomiting, fall in blood pressure, fast heart beat, collapse, disturbed consciousness up to coma (deep unconsciousness), epileptic fits, and difficulty in breathing up to cessation of breathing and death may occur. In such cases a doctor should be called immediately.

If you forget to take Tramadol Hydrochloride
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 Hydrochloride
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.

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 most common side effects during treatment with Tramadol Hydrochloride 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
- 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.
- urge to 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. 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 Hydrochloride. 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

- 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 Hydrochloride').

Drug Withdrawal

When you stop taking Tramadol Hydrochloride, 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 Hydrochloride, 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 Hydrochloride

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

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 use this medicine after the expiry date which is stated on the carton, blister and the bottle. The expiry date refers to the last day of that month.

For Each Alu/PVC/PVdC blister (60 g/m²): Store below 30 ºC.

For Each Alu/PVC/PVdC blister (120 g/m²), Alu/PVC/PE/PVdC blister (90 g/m²) and HDPE bottle:
This medicine does not require any special storage conditions.

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 Hydrochloride contains
The active substance is tramadol hydrochloride. Each capsule contains 50 mg tramadol hydrochloride.

The other ingredients are:
Capsule powder: Microcrystalline cellulose, sodium starch glycolate (Type A), colloidal anhydrous silica and magnesium stearate.
Capsule shell: Gelatin, iron oxide yellow (E172) and titanium dioxide (E171).
Printing ink: Shellac (E904), black iron oxide (E172) and propylene glycol (E1520).

What Tramadol Hydrochloride looks like and contents of the pack
Tramadol Hydrochloride are hard gelatin capsules with yellow opaque cap and yellow opaque body marked as ‘T50’ with black ink on cap containing a white to off white powder.

Tramadol Hydrochloride are supplied in following pack sizes:
Alu/PVC/PVdC blister (60 g/m²) in packs of 10, 30 and 100 capsules
Alu/PVC/PVdC blister (120 g/m²) in packs of 10, 30 and 100 capsules
Alu/PVC/PE/PVdC blister (90 g/m²) in packs of 10, 30 and 100 capsules
HDPE containers of 500 and 1000 capsules

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Amarox Limited
Congress House,

14 Lyon Road, Harrow,
Middlesex HA1 2EN
United Kingdom

Manufacturer
Amarox Limited
Congress House,
14 Lyon Road, Harrow,
Middlesex HA1 2EN
United Kingdom

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Please be ready to give the following information:

Product name	Reference number
Tramadol Hydrochloride 50 mg Capsules	PL 49445/0117

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