

Tramadol hydrochloride 50 mg/ml Solution for Injection or Infusion
tramadol hydrochloride

- ▶ **Read all of this leaflet carefully before you start using 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.
- ▶ 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.

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

What is in this leaflet

1. What Tramadol hydrochloride 50 mg/ml Solution for Injection or Infusion is and what it is used for
2. What you need to know before you are given Tramadol hydrochloride 50 mg/ml Solution for Injection or Infusion
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1. What Tramadol hydrochloride 50 mg/ml Solution for Injection or Infusion is and what it is used for

This medicine has been prescribed for you for the treatment of 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 receiving it suddenly. Your prescriber should have explained how long you will be receiving it for and when it is appropriate to stop, how to do this safely.

2. What you need to know before you are given Tramadol hydrochloride 50 mg/ml Solution for Injection or Infusion

You should not be given Tramadol hydrochloride 50 mg/ml Solution for Injection or Infusion if you:

- are allergic to tramadol hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- 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 50 mg/ml Solution for Injection or Infusion (see "Other medicines and Tramadol hydrochloride 50 mg/ml Solution for Injection or Infusion")
- are an epileptic and your fits are not adequately controlled by treatment
- have drunk enough alcohol to make you feel woozy or drunk
- have taken more than the prescribed dose of your sleeping tablets or other pain killers, which can slow down your breathing and reactions. (See section "Other medicines and Tramadol hydrochloride 50 mg/ml Solution for Injection or Infusion" for details)

You should not take this product for the treatment of withdrawal symptoms caused by opiates (morphine- like medicines).

Warnings and precautions

Talk to your doctor or nurse before being given Tramadol hydrochloride 50 mg/ml Solution for Injection or Infusion if you:

- have a head injury, breathing difficulties or severe liver or kidney problems.
- feel that you are going to faint
- are in a state of shock (cold sweat may be a sign of this)
- have a tendency towards epilepsy or fits 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 hydrochloride 50 mg/ml Solution for Injection or Infusion')
- 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 receive 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.
- experience 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 hydrochloride 50 mg/ml Solution for Injection or Infusion 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 50 mg/ml Solution for Injection or Infusion 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 50 mg/ml Solution for Injection or Infusion, 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 50 mg/ml Solution for Injection or Infusion).

Addiction can cause withdrawal symptoms when you stop receiving 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 receiving 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. Receiving higher doses or more frequent doses of opioid, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

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.

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. 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').

Sleep-related breathing disorders

Tramadol hydrochloride 50 mg/ml Solution for Injection or Infusion can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

Children and adolescents

Tramadol hydrochloride 50 mg/ml Solution for Injection or Infusion is not suitable for children below the age of 12 years.

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 hydrochloride 50 mg/ml Solution for Injection or Infusion

Tell your doctor or nurse if you are using, have recently used or might use any other medicines, including medicines obtained without a prescription. This is especially important with the following medicines as they may interact with your Tramadol hydrochloride 50 mg/ml Solution for Injection or Infusion:

- 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.
- Anticoagulants to thin your blood such as warfarin
- Medicines used to treat epilepsy such as carbamazepine.
- Ondansetron (prevents nausea)
- Monoamine oxidase inhibitors (moclobemide or phenelzine for depression, selegiline for Parkinson's disease).
- Medicines that act on the nervous system such as hypnotics, tranquillisers, sleeping pills and pain killers may make you feel drowsier or faint
- Gabapentin or pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain)
- medicines which may cause convulsions (fits), such as certain antidepressants
- if you are taking certain antidepressants, Tramadol hydrochloride 50 mg/ml Solution for Injection or Infusion may interact with these medicines and you may experience serotonin syndrome (see section 4 'Possible side effects').

Pregnancy and breast feeding

You should not be given Tramadol hydrochloride 50 mg/ml Solution for Injection or Infusion 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 are given Tramadol hydrochloride 50 mg/ml Solution for Injection or Infusion during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

You should not be given Tramadol hydrochloride 50 mg/ml Solution for Injection or Infusion while you are breastfeeding as tramadol passes into breast milk and will affect your baby. Alternatively, if you receive Tramadol you should stop breastfeeding.

Driving and using machines

Details regarding a new driving offence concerning driving after drugs have been taken in the UK may be found here:

<https://www.gov.uk/drug-driving-law>

Tramadol hydrochloride 50 mg/ml Solution for Injection or Infusion may cause drowsiness, dizziness and blurred vision and therefore may impair your reactions and your ability to drive.

- 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.

If you feel that your reactions are affected, do not use electric tools or operate machinery, and do not work without a firm hold!

Tramadol hydrochloride 50 mg/ml Solution for Injection or Infusion with alcohol

Do not drink alcohol during treatment with Tramadol hydrochloride 50 mg/ml Solution for Injection or Infusion as its effects may be intensified

Tramadol hydrochloride 50 mg/ml Solution for Injection or Infusion contains sodium

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

3. How Tramadol hydrochloride 50 mg/ml Solution for Injection or Infusion is given

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using Tramadol hydrochloride 50 mg/ml Solution for Injection or Infusion, 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).

Your nurse or doctor will give you the injection or infusion.

Your doctor will decide the correct dosage for you and how and when the injection or infusion will be given.

Since the injection or infusion will be given to you by a doctor or nurse, it is unlikely that you will be given too much.

If you think you have been given too much, you must tell the person giving you the injection or infusion.

If treatment with Tramadol hydrochloride 50 mg/ml Solution for Injection or Infusion is interrupted or finished too soon, pain is likely to return. If you wish to stop treatment on account of unpleasant effects, please tell your nurse or doctor.

If you stop being given Tramadol hydrochloride 50 mg/ml Solution for Injection or Infusion

You should 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.

Up to 1 in 1000 people may experience allergic reactions to Tramadol hydrochloride. If you have any difficulty breathing, a rash or itchy skin, a swollen face or tongue or difficulty in swallowing, stop taking this medicine immediately and tell your doctor straight away.

The most common side effects during treatment with Tramadol hydrochloride 50 mg/ml Solution for Injection or Infusion are dizziness and nausea, which occur in more than 1 in 10 people.

- Common: may affect up to 1 in 10 people**
- Fatigue
 - Sweating
 - Vomiting
 - Constipation
 - Dry mouth
 - Headache
 - Somnolence (you may feel drowsy, sleepy, weary or low in energy)

- 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 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 heartbeat (bradycardia)
 - Increase in blood pressure
 - Changes in appetite
 - 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.
- Abnormal sensations (e.g. itching, tingling, numbness), trembling, epileptic fits, muscle twitches, uncoordinated movement, transient loss of consciousness (syncope), speech disorders.
- Hallucination, confusional state, sleep disorders, delirium, anxiety and nightmares
- Psychological complaints may appear after treatment with Tramadol hydrochloride 50 mg/ml Solution for Injection or Infusion. 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 (changes in senses and recognition, which may lead to errors in judgment).
- Muscle weakness
- Blurred vision or dilated or constricted pupils
- Passing urine with difficulty or pain, passing less urine than normal (dysuria).

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

- Increase in liver enzyme values

Not known: frequency cannot be estimated from available data

- Dependence and addiction (see section "How do I know if I am addicted?").
- Low blood sugar (hypoglycaemia)
- Speech disorders
- Epileptic fits (convulsions) have occurred mainly at high doses of tramadol or when tramadol was taken at the same time as other medicines which may induce fits
- Hiccups
- 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 50 mg/ml Solution for Injection or Infusion').

Drug Withdrawal

When you stop receiving Tramadol hydrochloride 50 mg/ml Solution for Injection or Infusion, 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 receiving Tramadol hydrochloride 50 mg/ml Solution for Injection or Infusion, it could be a sign that you have become addicted.

- You need to receive the medicine for longer than advised by your prescriber
- You feel you need to receive 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 hydrochloride 50 mg/ml Solution for Injection or Infusion

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 label/ carton after "EXP." The expiry date refers to the last day of that month. The nurse or doctor will check that the injection or infusion is not past its expiry date before giving you the injection or infusion.

Your injection or infusion will be stored in a cool place at a temperature not above 30°C.

6. Contents of the pack and other information

What Tramadol hydrochloride 50 mg/ml Solution for Injection or Infusion contains

The active substance is tramadol hydrochloride. In Tramadol hydrochloride 50 mg/ml Solution for Injection or Infusion each ml of solution contains 50 mg of tramadol hydrochloride.

The other ingredients are sodium acetate trihydrate and water for injections.

What Tramadol hydrochloride 50 mg/ml Solution for Injection or Infusion looks like and contents of the pack

The solution for injection or infusion is supplied in 1 or 2 ml clear glass ampoules. 1, 5 or 10 ampoules supplied in each carton.

Marketing Authorisation Holder

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