

Tramadol Hydrochloride Injection **50mg/1ml, 100mg/2ml**

tramadol hydrochloride

- **Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

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 use Tramadol hydrochloride 50 mg/ml Solution for Injection or Infusion
3. How to use 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

Tramadol - the active substance in Tramadol hydrochloride 50 mg/ml Solution for Injection or Infusion - is a painkiller belonging to the class of opioids that acts on the central nervous system. It relieves pain by acting on specific nerve cells of the spinal cord and brain.

Tramadol hydrochloride 50 mg/ml Solution for Injection or

- 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.

Infusion is used for the treatment of moderate to severe pain.

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

Do not use 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)
- 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 50 mg/ ml Solution for Injection or Infusion (see “Other medicines and Tramadol hydrochloride 50 mg/ml Solution for Injection or Infusion”)
- if you are an epileptic and your fits are not adequately controlled by treatment
- if you have drunk enough alcohol to make you feel woozy or drunk



- if you 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 using Tramadol hydrochloride 50 mg/ml Solution for Injection or Infusion:

- if you have a head injury, breathing difficulties or severe liver or kidney problems.
- if you think that you are addicted to other pain relievers (opioids)
- if you feel that you are going to faint
- if you are in a state of shock (cold sweat may be a sign of this)
- if you have a tendency towards epilepsy or fits because the risk of a fit may increase

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

Tramadol hydrochloride 50mg/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 50mg/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 phenezeline 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
- selective serotonin re-uptake inhibitors (SSRI's) to treat depression such as fluoxetine. You may experience symptoms such as confusion, restlessness, fever, sweating, uncoordinated movement of limbs or eyes, uncontrollable jerking of muscles, or diarrhoea
- medicines which may cause convulsions (fits), such as certain antidepressants

Pregnancy and breast feeding:

Tramadol hydrochloride 50 mg/ml Solution for Injection or Infusion should not be given during pregnancy or while breast feeding. 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.

Tramadol is excreted into breast milk. For this reason, you should not be given Tramadol more than once during breast-feeding, or alternatively, if you receive Tramadol more than once, you should stop breast-feeding

Driving and using machines:

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

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 50mg/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 to use Tramadol Hydrochloride 50 mg/ml Solution for Injection or Infusion

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

You should not suddenly stop taking this medicine unless your doctor tells you to. If you want to stop taking your medicine, discuss this with your doctor first, particularly if you have been taking it for a long time. Your doctor will advise you when and how to stop, which may be by lowering the dose gradually to reduce the chance of developing unnecessary

side effects (withdrawal symptoms). Generally there will be no withdrawal symptoms when treatment with tramadol is stopped. However, on rare occasions, people who have been treated with tramadol for some time may feel unwell if the treatment is abruptly stopped. They may feel agitated, anxious, nervous or shaky. They may be confused, hyperactive, have difficulty sleeping and have stomach or bowel disorders. 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 treatment tell your nurse or 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.

- Allergic reactions to Tramadol hydrochloride have been reported. 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.
- You may suffer from convulsions (fits), headache, blurred vision or dilated or constricted pupils
- You may notice that you are sweating more or are flushed, develop a rash or become itchy or numb
- You may feel drowsy, sleepy, weary, low in energy or dizzy or may have difficulty in speaking
- You may develop muscle twitches, uncoordinated movement, transient loss of consciousness (syncope), a tingling sensation and trembling or muscle weakness
- Elevated liver enzymes may occur.
- You may experience changes in your heart beat (faster or slower) or high or low blood pressure.
- You may experience constipation, a dry mouth, appetite changes or diarrhoea
- You may experience psychic effects including: changes in mood, activity, behaviour or perception, hallucinations, confusion, restlessness, sleep disturbances, delirium, anxiety and nightmares
- You may experience nausea or vomiting, retching, feeling bloated or full
- Dependency on Tramadol may develop. Tell your doctor if you notice this

- Shortness of breath, slower breathing or worsening of asthma may occur
- You may find it difficult to pass urine
- You may experience a decrease in blood sugar levels, speech disorders or dilated or constricted pupils

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

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.

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.

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.

7.Manufactured in India by:

TAJ PHARMACEUTICALS LTD.

Mumbai, India

Unit No. 214.Old Bake House,

Maharashtra chambers of Commerce Lane,

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at:Gujarat, INDIA.

Customer Service and Product Inquiries:

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