Pharmacode position may change as per Supplier's m/c requirement & additional small pharma code may appear on the front / back panel

Tramadol hydrochloride N03877

Tramadol hydrochloride N03877

**Package leaflet: Information for the user**

## Tramadol hydrochloride 50 mg/ml solution for injection or infusion

tramadol hydrochloride

Important information about your medicine
- ► Your doctor or nurse will give you the injection or infusion.
- ► If this injection or infusion causes you any problems talk to your doctor, nurse or pharmacist.
- ► Please tell your doctor or pharmacist, if you have any other medical conditions or have an allergy to any of the ingredients of this medicine.
- ► Please tell your doctor or pharmacist, if you are taking any other medicines.

**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.

**What is in this leaflet**



### 1. What Tramadol hydrochloride solution for injection or infusion is and what it is used for

Tramadol - the active substance in this medicne - 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.
This medicine is used for the treatment of moderate to severe pain.

### 2. What you need to know before you use Tramadol hydrochloride solution for injection or infusion

**Do not use this medicine:**
- 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 this medicine (see "Other medicines and Tramadol hydrochloride 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 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 this medicine:**
- 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
- Suffer from depression and you are taking antidepressants as some of them may interact with tramadol (see 'Other medicines and Tramadol hydrochloride').
- 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').

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.

**Sleep-related breathing disorders**
Tramadol hydrochloride 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.

Talk to your doctor or pharmacist 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.

**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.

This medicinal product is not suitable for children below the age of 12 years.

**Other medicines and Tramadol hydrochloride 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 this medicine:
- 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
- medicines which may cause convulsions (fits), such as certain antidepressants
- The risk of side effects increases, if you are taking certain antidepressants, Tramadol hydrochloride solution for injection or infusion may interact with these medicines and you may experience serotonin syndrome (see section 4 'Possible side effects').

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.

**Pregnancy and breast feeding:**
This medicine 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.

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

**Driving and using machines:**
This medicine 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!

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**Information for the Healthcare Professional**

**Tramadol hydrochloride 50 mg/ml solution for injection or infusion**
**Please read this information carefully before using Tramadol hydrochloride 50 mg/ml solution for injection or infusion (referred to as Tramadol Injection). Further information is contained in the Summary of Product Characteristics.**

**Presentation**
Tramadol Injection is presented as a clear colourless solution in a Type-I clear glass ampoule. Each 1 ml ampoule contains 50 mg of tramadol hydrochloride.

**Dosage and Method of Administration**
Whenever solution and container permit, parenteral drug products should be inspected visually for particulate matter and discolouration prior to administration. Only a clear solution should be used.
Tramadol Injection is for parenteral injection either intramuscularly, by slow intravenous injection or diluted in solution for administration by infusion or patient controlled analgesia. The dose should be adjusted to the intensity of the pain and the sensitivity of the individual patient. The lowest effective dose for analgesia should generally be selected. The total daily dose of 400mg tramadol hydrochloride should not be exceeded, except in special clinical circumstances.
Tramadol Injection should not be given for longer than absolutely necessary. If long term pain treatment is necessary then careful regular monitoring should be carried out, with breaks in treatment if necessary.

**Adults and Children over 12 years**
The usual dose is 50 or 100mg 4 to 6 hourly by either intramuscular or intravenous routes. Intravenous injections must be given slowly over 2–3 minutes. The dose should be adjusted according to the severity of the pain and the response.
For post-operative pain, an initial bolus of 100mg is administered. During the 60 minutes following the initial bolus, further doses of 50mg may be given every 10-20 minutes, up to a total dose of 250mg including the initial bolus. Subsequent doses should be 50mg or 100mg 4-6 hourly up to a total daily dose of 400mg.

**Elderly**
A dose adjustment is not usually necessary in patients up to 75 years without clinically manifest hepatic or renal insufficiency. In elderly patients over 75 years elimination may be prolonged. Therefore, if necessary the dosage interval is to be extended according to the patient's requirements.

**Renal insufficiency/dialysis and hepatic impairment**
In patients with renal and/or hepatic insufficiency the elimination of tramadol is delayed. In these patients prolongation of the dosage intervals should be carefully considered according to the patient's requirements
**Children under 12 years** Not recommended.

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**Tramadol hydrochloride solution for injection or infusion with food, drink and alcohol:**
Do not drink alcohol during treatment with this medicine as its effects may be intensified

**This medicine contains** sodium. This medicinal product contains less than 1 mmol sodium (1.4mg) per 2ml dose i.e. essentially 'sodium - free'

## 3. How to use Tramadol hydrochloride 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 this medicine 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 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 after-effects 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 or nurse.

## 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**
- Hiccups- Not Known (cannot be estimated from the available data)
- 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'). Not Known (cannot be estimated from the available data)

**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).

If you think this injection or infusion is causing you **side effects,** or you are at all worried, **talk to your doctor, nurse or pharmacist.**

**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 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 carton and label 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.

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 1ml ampoule contains 50 mg of tramadol hydrochloride.
Each 2 ml ampoule contains 100 mg of tramadol hydrochloride.

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

**What Tramadol hydrochloride solution for injection or infusion looks like and contents of the pack:**
Solution for injection or infusion.

Clear and colourless solution.
Type-I clear glass ampoule containing either 1 ml or 2 ml of injection solution. Ampoules are placed in a preprinted carton. Cartons contain either 5, 50 and 100 ampoules.
Not all pack sizes may be marketed.

**Marketing Authorisation Holder**
Milpharm Limited
Ares Block, Odyssey Business Park
West End Road
Ruislip HA4 6QD
United Kingdom

**Manufacturer**
APL Swift Services (Malta) Limited
HF26, Hal Far Industrial Estate, Hal Far
Birzebbugia, BBG 3000
Malta

or

Milpharm Limited
Ares Block, Odyssey Business Park
West End Road
Ruislip HA4 6QD
United Kingdom

**This leaflet was last revised in 10/2021.**

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**Contraindications**
Tramadol Injection should not be given to patients who have previously demonstrated hypersensitivity towards tramadol or any of the other ingredients in this medicine. Tramadol Injection should not be given to patients suffering from acute intoxication with alcohol, hypnotics, centrally acting analgesics, opioids or psychotropic drugs. In common with other opioid analgesics, tramadol should not be administered to patients who are receiving monoamine oxidase inhibitors or within two weeks of their withdrawal. Tramadol Injection is contraindicated in patients with epilepsy not adequately controlled by treatment. Tramadol must not be used in narcotic withdrawal treatment.

**Pharmaceutical Information**
**Excipients** Sodium acetate trihydrate and Water for Injections.
**Incompatibilities**
Precipitation will occur if Tramadol hydrochloride Injection is mixed in the same syringe with injections of diazepam, diclofenac sodium, indomethacin, midazolam and piroxicam.
**Shelf-life** 3 years
**Storage Precautions** Keep ampoule in the outer carton. This medicinal product does not require any special storage conditions.
**Nature of Container** Type-I clear glass ampoule containing either 1 ml or 2 ml of injection solution. Ampoules are placed in a pre-printed carton. Cartons contain either 5, 50 and 100 ampoules.

**Instructions for Use and Handling.**
The prepared infusion solution should be made up immediately before use.
Tramadol Hydrochloride solution for injection/infusion is physically compatible and chemically stable at controlled room temperature (i.e. 15-25°C) for up to 24 hours with 4.2% Sodium Bicarbonate Solution and Ringer's solution or up to 5 days when mixed with the following diluents for infusion over the concentration range of 0.5 mg/ml to 4.0 mg/ml.
- 0.9% Sodium Chloride Intravenous Infusion
- 5% Dextrose Intravenous Infusion
- 0.18% Sodium Chloride and 4% Dextrose Intravenous Infusion
- Ringer Lactate Solution
- Haemaccel

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would not normally be longer than 24 hours at 2 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

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