PACKAGE LEAFLET:
Information for the patient

# TRAMADOL

Solution for injection – 100 mg / 2 ml
*(Tramadol hydrochloride)*

**Read this leaflet carefully before you start taking this medicine.**

- 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 illnes are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**In this leaflet:**


1. What Tramadol is and what it is used for
2. Before you take Tramadol
3. How to take Tramadol
4. Possible side effects
5. How to store Tramadol
6. Other information


## 1. WHAT TRAMADOL IS AND WHAT IT IS USED FOR

Tramadol contains as active substance tramadol hydrochloride. Tramadol hydrochloride is an opioid analgesic that is used for the treatment of moderate to severe pain such as traumatic pain (caused by injuries, fractures), severe neuralgia, pain caused by tumors or a heart attack and pain after diagnostic or therapeutic procedures.
Your doctor may have given Tramadol for another purpose. Ask your doctor if you want to know why you were given this drug.

## 2. BEFORE YOU TAKE TRAMADOL

**Do not take Tramadol if you:**

- are hypersensitive (allergic) to tramadol hydrochloride, other opioids or any other component of the drug;
- suffer from severe renal impairment (creatinine clearance less than 10 mL/minute);
- have acute intoxication with alcohol, hypnotics, narcotics, centrally acting analgesics, opioids, or psychotropic drugs;
- are receiving monoamine oxidase inhibitors (MAOIs) or if you are within two weeks of their withdrawal (See section “Taking other medicines”).

Tramadol is not recommended in children under 12 years and is contraindicated in infants under 1 year old.
Opioid analgesics are generally contraindicated in acute respiratory depression and obstructive airways disease. These drugs are also contraindicated or should be used with great caution in patients with convulsive disorders, head injuries, or raised intracranial pressure. Opioid analgesics should not be given to comatose patients.

**Take special care with Tramadol**
Ask your doctor before you take Tramadol.
Opioids should be used with caution in patients with impaired respiratory function (avoid in chronic obstructive pulmonary diseases) and asthma (avoid during an acute attack), hypotension, shock, myasthenia gravis, prostatic hypertrophy, obstructive or inflammatory bowel disorders and diseases of the biliary tract.
A reduced dose is recommended in elderly or debilitated patients, in hypothyroidism,and in adrenocortical insufficiency.
Long -term use of opioid analgesics is associated with the development of psychological and physical dependence. Although this is rarely a problem with therapeutic use and tramadol may have lower potential for producing dependence than other opioids, caution is advised if prescribing for patients with a history of drug dependence.
Abrupt withdrawal after long-term treatment should be avoided.

**Taking other medicines:**
Inform your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those obtained without a prescription.

Inform your doctor, especially if you are being treated with the following medications:

- *anaesthetics:* opioid analgesics possibly enhance effects of intravenous general anaesthetics and volatile liquid general anaesthetics;
- *anticoagulants:* tramadol enhances the anticoagulant effect of coumarins;
- *antidepressants:* possible increased serotonergic effects when tramadol given with duloxetine, mirtazapine or venlafaxine; possible increased serotonergic effects and increased risk of convulsions when tramadol given with MAOIs (concomitant use and use within two weeks after stopping MAOIs should be avoided, see section 2 “Do not take Tramadol”); excitation or depression (hypertension or hypotension) when opioid analgesics given with moclobemide (the dose of opioid analgesics may need to be reduced); increased risk of central nervous system toxicity when tramadol given with selective serotonin reuptake inhibitors or tricyclic antidepressants;
- *carbamazepine:* effects of tramadol reduced;
- *antipsychotics:* increased risk of convulsions;
- *anxiolytics and hypnotics:* increased sedative effect;
- *atomoxetine:* possible increased risk of convulsions;
- *barbiturates:* central nervous system effects of opioid analgesics possibly increased by barbiturates;
- *ondansetron:* antagonised effects of tramadol;
- *selegiline;*
- *drugs for the treatment of ulcers:* metabolism of opioid analgesics inhibited by cimetidine;
- *domperidone and metoclopramide:* opioid analgesics antagonise gastro-intestinal effects.

**Taking Tramadol with food and drinks**
If opioid analgesics are concurrently taken with alcohol, sedative and hypotensive effects are enhanced.

**Pregnancy and breastfeeding**
*Pregnancy*
Tramadol crosses the placenta.
There are no sufficient data on the safety of tramadol during pregnancy. Long-term use during pregnancy may result in physical dependence and postpartum withdrawal in the newborn.
In these conditions, tramadol should be given only if the potential benefit justifies the potential risk to the fetus.

*Breastfeeding*
Tramadol and its metabolites pass in small amounts in human breast milk (about 0.1 % of the maternal dose). However, there are no data on the effects of tramadol in breastfeeding.
In these conditions, tramadol should be given during breastfeeding only if the benefit outweighs the risk.
Ask your pharmacist or doctor for advice before taking this drug.

**Driving and using machines**
Tramadol may cause drowsiness and thus this drug may affect the ability of the patient to drive or use machines. Concomitant consumption of alcohol enhances this effect.

## 3. HOW TO TAKE TRAMADOL

Always take Tramadol exactly as your doctor has told you. If you are not sure contact your doctor or pharmacist.

*Adults and children over 12 years*
The recommended dose is 50 to 100 mg every 4 to 6 hours, by intramuscular or intravenous injection over 2 to 3 minutes, or by intravenous infusion.
For the treatment of postoperative pain, the initial dose is 100 mg followed by 50 mg every 10 to 20 minutes; if necessary to a total maximum (including the initial dose) of 250 mg in the first hour. Thereafter, doses are 50 to 100 mg every 4 to 6 hours up to a total daily dose of 600 mg.

*Children under 12 years*
Tramadol is not recommended for children 1-12 years. This medicine is contraindicated in infants under 1 year (see section 2, “Do not take Tramadol”).

*Patients with hepatic and renal impairment*
In patients with hepatic impairment or with a creatinine clearance less than 30 mL / minute (renal impairment), it is recommended that the interval between doses should be extended in 12 hours. Tramadol should not be given to patients with severe renal impairment (creatinine clearance less than 10 mL / minute) (see section 2, "Do not take Tramadol").

*Other special patient groups*
In elderly or debilitated patients, in hypothyroidism, or in adrenocortical insufficiency, is recommended a reduced dose (see section 2, “Take special care with Tramadol”).

**If you take more Tramadol than you should**
If you take more Tramadol than you should, or if the children have accidentally taken this drug, please contact your doctor, hospital or emergency call to get an opinion on the risk and advice on the actions that should be taken.
Generally, the symptoms of overdosage with tramadol are similar to those of other analgesic drugs with central action (opioids). These include miosis, vomiting, cardiovascular collapse, consciousness disorders up to coma, convulsions and respiratory impairment up to respiratory blockage.
In case of overdose, the emergency measures should be taken to maintain open the airways (aspiration) and to keep respiration and blood circulation under control. The antidote, in the case of respiratory blockage is naloxone, while for the treatment of convulsions is used diazepam, as intravenous injection.

**If you forget to take Tramadol**
If you forget taking one dose (or more than one dose), take the next dose in its usual time. Do not take a double dose (or larger) to make up a forgotten dose(s).

**If you stop taking Tramadol**
Long-term use of opioid analgesics can cause psychological and physical dependence. In these cases, abrupt withdrawal of the treatment should be avoided (see section 2, "Take special care with Tramadol").
If you have further questions on the use of this product, ask your doctor or pharmacist.

## 4. POSSIBLE SIDE EFFECTS

Like all medicines, Tramadol can cause side effects, although not everybody gets them.
The most common side-effects of opioid analgesics are nausea and vomiting (particularly in initial stages), constipation, dry mouth, and biliary spasm; larger doses produce muscle rigidity, hypotension, and respiratory depression. Other common side-effects are bradycardia, tachycardia, palpitation, oedema, postural hypotension, hallucinations, vertigo, euphoria, dysphoria, mood changes, dependence, dizziness, sleep disturbances, headache, sexual dysfunction, difficulty with micturition, urinary retention, ureteric spasm, miosis, visual disturbances, sweating, flushing, rash, urticaria, and pruritus.
It should be noted that some of these typical opioid analgesics adverse effects (e.g. respiratory depression, constipation and dependence) may be fewer following tramadol hydrochloride treatment.
Tramadol hydrochloride administration is also associated with diarrhea, fatigue, less commonly retching, gastritis, and flatulence and rarely anorexia, syncope, hypertension, bronchospasm, dyspnoea, wheezing, seizures, paraesthesia, and muscle weakness. Blood disorders have also been reported.
Long-term use of opioid analgesics can cause hypogonadism and adrenal insufficiency in both men and women. This can lead to amenorrhoea, reduced libido, infertility, depression, and erectile dysfunction.
Long-term use of opioid analgesics has been also associated with a state of abnormal pain sensitivity (hyperalgesia).
Inform your doctor or pharmacist if you get these side effects or any side effect not listed in this leaflet.

## 5. HOW TO STORE TRAMADOL

Keep out of the sight and reach of children!
Do not use Tramadol after the expiry date which is stated on the package.
Do not store above 25°C!
Keep in the original package to protect from light.

## 6. OTHER INFORMATION

**What Tramadol – Solution for injection 100 mg / 2 ml contains**
**The active substance** is tramadol hydrochloride.
1 ampoule of 2 ml contains 100 mg tramadol hydrochloride.
Other components are: glucose, hydrochloric acid, water for injections.

**Contents of the pack:**
Box with 10 ampoules of 2 ml
Box with 100 ampoules of 2 ml (for hospital use).

**Explanatory of the illustration icons on the packaging:**

According to medical prescription.

Content. Warning.

Solution for injection.

**Marketing Authorisation Holder and Manufacturer**


**PROFARMA Sh.a.**
Rruga "Myslym Keta"
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Tirana - ALBANIA


**This leaflet was last revised in June 2013.**

SPECIFICATION

CROPING AREA 15 X 25 cm

**PAY ATENTION**, all the layers are visible. If you have to print this document please check or uncheck the specific layers.