

TRAMADOL STADA INJECTION

Tramadol hydrochloride 100mg/2ml

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What Tramadol STADA Injection is used for

- Treatment of moderate to severe pain

How Tramadol STADA Injection works

- Tramadol STADA Injection is a painkiller belonging to the class of the opioids that acts on the central nervous system. It relieves pain by acting on specific nerve cells of the spinal cord and brain.

Before you use Tramadol STADA Injection

When you must not take it

- if you are allergic to the active substance tramadol hydrochloride or to any of the other ingredients of Tramadol STADA Injection
- in acute intoxication with alcohol, analgesics, sedatives or other psychotropic drugs
- if you are also taking monoamine oxidase (MAO) inhibitors
- if you have taken MAO inhibitors within two weeks of when you will start taking Tramadol STADA Injection

Before you start to take it

You should tell your doctor if

- The pressure inside your skull is higher than normal.
- You have difficulty in breathing
- You suffer from consciousness disorders
- You suffer from a liver or kidney disease
- You think that you are addicted to other pain relievers

Taking other medicine

- Please tell your doctor or pharmacist if you are using or have recently used any other medicines, including medicines obtained without a prescription.
- DO NOT take Tramadol STADA Injection with monoamine oxidase inhibitors (MAOI), or 2 weeks before and after taking these medicines. MAOs are medicines used for depression.
- The effect of Tramadol STADA Injection may be greater if you are:
 - also taking other medicines which act on your central nervous system
 - drinking alcohol
- You may feel drowsier or feel that you might faint. If this happens tell your doctor.
- You should take care if you are also taking:
 - Medicines which may cause convulsions, for instance medicines for the treatment of psychological diseases. The risk having a fit may increase if you take Tramadol STADA Injection at the same time.
 - Selective serotonin re-uptake inhibitors used to treat depression.

How to take Tramadol STADA Injection

How much to take

- Always take Tramadol Stada Injection exactly as your doctor has told you. You should check with your doctor or pharmacist if you are

not sure. Unless otherwise prescribed, the following dosage guidelines apply. The recommended dosage is guidelines only. In principle, the lowest effective analgesic dose should be chosen.

- In the treatment of chronic pain, strict time-tabling of doses is preferred. Tramadol dosage should be adjusted to the severity of pain and the patient's individual sensitivity.
- For adults and juveniles over the age of 14 (single dose): 1 ampoule Tramadol Stada Injection equivalent to 100 mg Tramadol hydrochloride.
- If the analgesic effect is inadequate, a second single dose may be administered after 30-60 minutes. In severe pain, if clinical experience suggests that a higher analgesic requirement can be expected, the higher dose of Tramadol may be used initially.
- The recommended dose for postoperative pain is 100 mg initially then 50mg every 10-20 minutes if necessary during first hour to the total max of 250 mg (including initial dose in first hour, then 50-100 mg every 4-6 hours max. 600 mg daily).
- For the treatment of severe postoperative pain, Tramadol doses of up to 500 mg/4h may be used in an on-demand analgesia system. This, however, requires monitoring facilities and special apparatus.
- In children aged from 1 year upwards, experience to date suggests that Tramadol hydrochloride may be used at doses of 1-2 mg/kg body weight. The duration of action of Tramadol hydrochloride is on average 4-8 hours, depending on the severity of pain. Daily doses of up to 4 ampoules of Tramadol Stada (400 mg tramadol hydrochloride) are generally adequate.
- Dosage of tramadol hydrochloride should be reduced in certain patients with kidney or liver impairment by decreasing the frequency of

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administration. In patients with kidney impairment, the dosing interval of Tramadol should be increased to 12 hours. The maximum recommended daily dose is 200 mg.

- Adults and children 14 years and older with liver impairment may receive a tramadol hydrochloride dosage of 50 mg every 12 hours.

When to take it

- Tramadol STADA Injection can be taken without relation to mealtimes.

How long to take it

- Your doctor will tell you for how long you should take Tramadol STADA Injection.

If you forget to take it

- If you forget to take a dose of Tramadol STADA Injection just take the next dose at the usual time. DO NOT take a double dose to make up for the missed one.

If you take too much (overdose)

- After taking very high doses, constricted or dilated pupils, fast hear beat, disturbed consciousness up to coma (deep unconsciousness), epileptic fits, and difficulty in breathing up to cessation of breathing may occur. Gastric lavage may be useful in oral intoxication. In such cases, contact your doctor or go to your nearest emergency department immediately! Your doctor will treat the symptoms of Tramadol STADA Injection overdose.

While you are using Tramadol STADA Injection

Things you must do

- Always take Tramadol STADA Injection exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Things you must not do

- Do not drink alcohol during treatment with Tramadol STADA Injection as its effect may be intensified.
- You should not take Tramadol STADA Injection long-term during pregnancy.
- Don't take more than a single dose of Tramadol STADA Injection while breast-feeding your baby.
- Do not use Tramadol STADA Injection after the expiry date.

Things to be careful of

- Even when used as directed, tramadol may have such a significant effect on mental alertness that patients should not drive a car or other vehicle nor operate machinery while using Tramadol STADA Injection.
- Tramadol has a dependence potential. Prolonged use results in the development of tolerance, mental and physical dependence. Tramadol and other opioids show cross-tolerance.
- Pregnancy
 - Chronic use of Tramadol should be avoided during three trimesters of pregnancy.
- Breast-feeding
 - Very small amounts of Tramadol STADA Injection may pass through your breast-milk to your infant. Don't take more than a single dose of Tramadol STADA Injection while breast-feeding your baby. You can continue breast feeding if you have only taken a single dose of Tramadol STADA Injection.

Side effects

- Very common: nausea, Dizziness
- Common: Dry mouth, Headache, Sweating, Drowsiness, fatigue
- Uncommon:

- Gastrointestinal irritation (a feeling of pressure in the stomach, bloating)
- Vomiting
- Constipation
- Cardiovascular regulation including feeling your heartbeat (palpitations), rapid heartbeat (tachycardia), feeling dizzy or faint on standing (postural hypotension), when there is not enough circulation of blood because the heart does not work properly (circulatory collapse)
- Skin reactions including itching (pruritus) and rash.
- Rare:
 - Changes in appetite
 - Changes in mood – usually high spirits (elation), occasionally an unpleasant mood (dysphoria)
 - Changes in activity (usually less active, occasionally more active)
 - Changes in your ability to think and feel things clearly such as: making decisions and perception disorders
 - weak muscles
 - passing urine with difficulty or pain, passing less urine than normal
 - allergic reaction
 - extending to shock
- 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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

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Storage and Disposal of Tramadol STADA Injection **Date of revision**
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Storage

- Keep out of the reach and sight of children.
- Do not store above 30°C.

Serial Number

Disposal

- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

What it looks like

- Tramadol STADA Injection is a clear, colourless solution available in packs of 5 ampoules of 2 ml injectable solution.

Ingredients

- Active ingredient:
The active substance is tramadol hydrochloride.
- Inactive ingredient:
The other ingredients are sodium acetate and water for injections.

MAL number(s):

MAL07122770ACSZ

Manufacturer

B. BRAUN MELSUNGEN AG.
MISTELWEG 2, 12357 BERLIN,
GERMANY

Product Registration Holder

DKSH Malaysia Sdn Bhd,
B-11-01, The Ascent, Paradigm
No.1, Jalan SS7/26A, Kelana Jaya
47301 Petaling Jaya
Selangor Darul Ehsan