

PATIENT INFORMATION LEAFLET

TRAMADOL 50 mg/mL SOLUTION FOR INJECTION OR INFUSION

Please read all of this leaflet carefully before being given Tramadol Injection.

- Keep this leaflet as you may need to refer to it again.
- If you want to know more about Tramadol Injection, or have any questions, you should ask your doctor or nurse.

In this leaflet:

- 1. What Tramadol Injection is and what it is used for**
- 2. Before you are given Tramadol Injection**
- 3. How Tramadol Injection should be given**
- 4. Possible side effects**
- 5. Storing Tramadol Injection**
- 6. Further information**

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

Tramadol belongs to a group of medicines known as analgesics or “pain-killers”. Tramadol is used to relieve pain and can also be used to prevent pain.

2. BEFORE YOU ARE GIVEN TRAMADOL INJECTION

You must NOT be given Tramadol Injection and you should talk to your doctor immediately if:

- you are allergic to tramadol hydrochloride or any of the other ingredients of the solution. Allergic reactions to tramadol could include skin rash, swelling of the face, wheezing or difficulty breathing
- you are epileptic and your fits are not well controlled by treatment
- the patient is a child under 12 years of age
- you are pregnant or breast-feeding
- you are taking any of the following medicines:
 - sleeping tablets or tranquillizers such as nitrazepam
 - other pain-killers such as codeine or morphine
 - psychotropic medicines such as chlorpromazine
- a monoamine oxidase inhibitor used to treat depression, or if you have taken one in the past two weeks
- you have recently been drinking alcohol.

It should not be used in narcotic drug withdrawal treatment.

Tell your doctor before you are given Tramadol Injection if:

- you have liver or kidney disease. You may need a lower dose or a longer interval between doses
- you have a head injury or brain disease
- you have a problem that makes you faint or feel faint
- you are in a state of shock. You may feel light headed, faint, cold or clammy or look pale
- you suffer from epilepsy, convulsions or seizures (fits) or have had them in the past
- you suffer from asthma, other lung diseases or have difficulty in breathing.
- you think you may be addicted to other pain relievers

Tramadol may lead to addiction.

In patients with a tendency to drug abuse, Tramadol Injection should only be given for short periods under strict medical supervision.

Taking/using other medicines

Tell your doctor if you are taking, or have recently taken, any of the following medicines. This is important because Tramadol Injection could alter how other medicines work.

- tricyclic antidepressants, such as amitriptyline, as this may increase the chance of having a fit (although this is very rare)
- carbamazepine, a treatment for epilepsy, as this may reduce the effectiveness of the tramadol
- triptans, such as sumatriptan, used to treat migraines, as this may increase the effectiveness of the triptans
- coumarin anticoagulants, used to thin the blood, such as warfarin, as this may alter the effectiveness of the anticoagulant
- selective serotonin reuptake inhibitors (SSRI's), used to treat depression, such as fluoxetine, as this may increase the effect of the SSRI's
- lithium, used to treat psychotropic disorders, as this may alter the effect of lithium
- pentazocine, nalbuphine or buprenorphine (pain killers)
- ondansetron, used to prevent nausea and vomiting.

Tell your doctor if you are taking, or have recently taken any other medicine, including those obtained without a prescription.

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

Pregnancy and breastfeeding

There is very little information on the safety of tramadol in pregnancy, therefore Tramadol Injection should not be used if you are pregnant.

Chronic use during pregnancy may lead to withdrawal symptoms in newborns.

Tramadol may be harmful to the breast fed baby. The use of Tramadol Injection is not generally recommended during breastfeeding. However, after a single dose of tramadol it is not usually necessary to interrupt breastfeeding.

Driving and using machinery

Tramadol Injection may cause drowsiness, dizziness or blurred vision, these effects may be increased by alcohol and other depressants. Do not drive or use machinery if you are affected.

3. HOW TRAMADOL INJECTION SHOULD BE GIVEN

Your doctor or nurse will usually give you Tramadol Injection. The solution may be given by an injection into either a vein or muscle.

If you are in hospital you may receive tramadol through a drip (infusion) or from a small machine that allows you to have tramadol when you need it by pushing a button. The doctor or nurse will explain how to use the machine.

The usual dose is one injection of 50mg or 100mg every 4 to 6 hours. After an operation you may need injections more often. Tramadol Injection should not be given to children under 12 years of age.

In general, the lowest dose to relieve pain should be given for the shortest possible time.

If you receive too much Tramadol Injection. If you think you have been given or have given yourself too much Tramadol Injection tell a doctor or nurse immediately.

If you stop receiving Tramadol Injection Rarely when some people stop treatment with tramadol they get withdrawal symptoms. These **symptoms include agitation, nervousness, shaking, hyperactivity and difficulty in sleeping.**

4. POSSIBLE SIDE EFFECTS

Like all medicines, Tramadol Injection can cause side effects. However, do not be alarmed, as most patients do not have problems with this medicine.

Tell your doctor or a nurse immediately if you experience any of the following:

- swelling around the throat, tightness in your chest or difficulty in breathing.

You may have had an allergic reaction, these are rare but, if severe, can be serious and you may need urgent medical attention.

Tell a doctor or nurse if you get any of the following

Other side effects:

Very common side effects (occurring in more than 1 in 10 patients):

- nausea, dizziness.

Common side effects (occurring in less than 1 in 10 patients):

- headache, drowsiness, fatigue
- vomiting, constipation, dry mouth, sweating.

Uncommon side effects (occurring in less than 1 in 100 patients):

- changes in heart beat or rhythm which may make you feeling faint or dizzy especially if you stand up quickly
- retching, stomach irritation or feeling bloated
- diarrhoea
- rash.

Rare side effects (occurring in less than 1 in 1000 patients):

- changes in appetite, abnormal touch sensations, trembling, difficulty breathing, fits, fainting
- slowing of the heart rate, increased blood pressure
- nightmares, disturbed sleep patterns, hallucinations (seeing things), feeling confused, changes in mood, activity or awareness, anxiety
- blurred vision
- muscle weakness or twitching, abnormal coordination
- increase in liver enzymes
- difficulty or pain passing water (urine)
- worsening of asthma, shortness of breath
- Rarely when some people stop taking tramadol they get withdrawal symptoms. These symptoms include agitation, nervousness, shaking, hyperactivity and difficulty in sleeping. Very rarely panic attacks, severe anxiety, hallucinations, tinnitus or abnormal skin sensations, as well as confusion, delusions, personalisation, derealisation and paranoia, have occurred.

Other side effects (frequency unknown):

- speech disorder
- dilation of the pupil.

If you notice any other side effects please tell your doctor or nurse.

5. STORING TRAMADOL INJECTION

Do not store above 30°C.

6. FURTHER INFORMATION

What is in this medicine:

Each 2 ml ampoule contains 100 mg of tramadol hydrochloride. The ampoules also contain sodium acetate trihydrate and water for injections.

What this medicine looks like and contents of the pack:

Tramadol Injection is a clear colourless solution. Each pack contains 1/5/10 glass ampoules

Marketing authorisation holder:

MSN Laboratories Private Limited,
“MSN HOUSE” Plot No.C24,
Industrial Estate, Sanathnagar,
Hyderabad 500 018, Telangana, India.