

Read this leaflet carefully before taking the medicine.

- Keep this leaflet. You may need to reread it again.
- If you have any question, consult your doctor or pharmacist
- This medicine has been prescribed to you personally and you must not give it to others. It can harm them, even if the symptoms are the same as yours.

This leaflet contains:

1. WHAT IS TRAMADOL NORMON 100 mg/2 ml INJECTABLE SOLUTION, AND WHEN IT IS USED
2. BEFORE USING TRAMADOL NORMON 100 mg/2 ml INJECTABLE SOLUTION
3. HOW TO USE TRAMADOL NORMON 100 mg/2 ml INJECTABLE SOLUTION
4. POSSIBLE SIDE EFFECTS
5. STORAGE OF TRAMADOL NORMON 100 mg/2 ml INJECTABLE SOLUTION
6. INSTRUCTIONS FOR SANITARY STAFF

TRAMADOL NORMON 100 mg/2 ml INJECTABLE SOLUTION

The active ingredient is tramadol hydrochloride. Each ampoule contains 100 mg of tramadol (I.N.N.) hydrochloride. The excipients are: water for injection and sodium acetate.

MARKETING AUTHORIZATION HOLDER AND MANUFACTURER:

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1. WHAT IS TRAMADOL NORMON 100 mg/2 ml INJECTABLE SOLUTION, AND WHEN IT IS USED:

TRAMADOL NORMON 100 mg/2 ml INJECTABLE SOLUTION is presented as a single ampoule with injectable solution, packed in boxes containing 5 ampoules.

TRAMADOL NORMON 100 mg/2 ml INJECTABLE SOLUTION is indicated for the relief of moderate to severe pain.

2. BEFORE USING TRAMADOL NORMON 100 mg/2 ml INJECTABLE SOLUTION:

■ Do not use TRAMADOL NORMON 100 mg/2 ml INJECTABLE SOLUTION:

- If you have a known hypersensitivity to tramadol or to any of its components.
- If you had suffered an acute poisoning with alcohol, hypnotics, analgesics, opioids or psychotropics.
- If you are taking MAO inhibitors or you have taken them within the last two weeks.
- Tramadol must not be used to treat withdrawal symptoms.
- Consult your doctor in case of any doubt.

■ Take special care when taking TRAMADOL NORMON 100 mg/2 ml INJECTABLE SOLUTION:

- If you have dependence on opiates or you are sensitive to them.
- If you have head injuries or diseases of the brain, shock (severe blood circulation failure), impairment of consciousness or disorders affecting the respiratory function.
- If you suffer from epilepsy or convulsions, tramadol may increase the risk of an epileptic crisis.

Patients may develop tolerance as well as mental and physical dependence during long term treatment with tramadol. In patients who show a tendency to drug misuse or substance dependence, tramadol should administered only for a short period and under strict medical supervision.

■ **Pregnancy:** TRAMADOL NORMON 100 mg/2 ml INJECTABLE SOLUTION passes through the placenta and should not be used during pregnancy. Consult your doctor or pharmacist before using a medicine.

■ **Lactation:** TRAMADOL NORMON 100 mg/2 ml INJECTABLE SOLUTION is excreted in the breast milk and therefore should not be used during lactation. Consult your doctor or pharmacist before using a medicine.

■ **Driving and use of machinery:** TRAMADOL NORMON 100 mg/2 ml INJECTABLE SOLUTION may cause drowsiness and therefore you should not drive nor use dangerous machinery if you are taking tramadol. Such effects might be increased when tramadol is taken in conjunction with alcohol or with other psychotropic drugs.

■ **Use of other medicines:** Inform your doctor or pharmacist if you are taking or have recently taken any other medicine, including those acquired without medical prescription. Some drugs can affect the action of others.

TRAMADOL NORMON 100 mg/2 ml INJECTABLE SOLUTION interacts with the following drugs:

- Medicines used to treat depression: As MAO (monoamine oxidase) inhibitors, Selective serotonin reuptake inhibitors, Tricyclic antidepressants.
- Substances, which act as SNC depressors, including alcohol: Can increase the effect of SNC depressors.

- Carbamazepine: Reduces analgesic effect and duration of action of tramadol.
- Drugs used to relief pain, such as mixed agonist/ antagonist (e.g. buprenorphine, nalbuphine, pentazocine): Reduce the analgesic action of Tramadol.
- Antipsychotics: It may increase the occurrence of convulsions.

3. HOW TO USE TRAMADOL NORMON 100 mg/2 ml INJECTABLE SOLUTION:

Follow these instructions unless otherwise advised by your doctor. Remember taking your medicine. As with others analgesics, the dosage for adults and young people over 12 years of age should be adjusted to the severity of the pain and the individual clinical response of the patient.

TRAMADOL NORMON 100 mg/2 ml ampoules is administered by intravenous, intramuscular or subcutaneous injection.

Adults and young people over 12 years: For severe pain, it should be administered 100 mg as the initial dose during the first hour, after this dose it could administered complementary dosages of 50 mg every 10-20 min, not exceeding a total dose of 250 mg. If pain persists, a dose of 50 or 100 mg every 6 to 8 hours can be administered without exceeding the total daily dose of 400 mg for moderate pain, a single dose of 50 or 100 mg is administered during the first hour.

Children under 12 years: It can be administered from 1 to 1.5 mg/kg body weight as a single dose.

Elderly patients: Dose adjustment is not usually necessary in patients up to 75 years of age unless they present impairment of hepatic or renal function. In patients over 75 years of age, the intervals between doses should be lengthened in accordance with individual needs.

Hepatic and/or renal function impairment: Tramadol should not be administered to patients with serious hepatic and/or renal impairment. In less severe cases a lengthening of the interval between doses should be considered.

Tramadol should not be used during more time than the absolutely necessary. Treatment periods, in general, must be limited and intermittent. If a patient needs a long term treatment with Tramadol, depending on the severity and nature of the disease, careful and regular monitoring will be necessary to determine whether it is necessary to continue the treatment and for how long.

■ If you have received more TRAMADOL NORMON 100 mg/2 ml INJECTABLE SOLUTION than you should, consult your doctor or pharmacist. The symptoms of overdose are: Miosis, vomiting, circulatory collapse, clouding of consciousness, convulsions and respiratory depression.

Doctor information: In case of overdose, keep the airway clear and proceed emptying the stomach by inducing vomiting if the patient is conscious, or by gastric washout. Naloxone can be administered as an antidote in case of respiratory depression.

■ If you forgot the administration of TRAMADOL NORMON 100 mg/2 ml INJECTABLE SOLUTION, do not receive a double dose to compensate the forgotten doses.

4. POSSIBLE SIDE EFFECTS:

As any drug, TRAMADOL NORMON 100 mg/2 ml INJECTABLE SOLUTION could have undesirable effects:

Frequently (more than 10%): Nausea and giddiness. **Occasionally (1-10%):** Vomiting, constipation, sweating, dryness of the mouth, headaches and dizziness. **Rarely (less than 1%):** Disorder of cardiovascular regulation specially after intravenous administration and in patients who are under physical stress, arcades, gastrointestinal irritation and cutaneous reactions. **Very rarely (less than 0.1%):** Muscular weakness, changes in appetite and disorders of micturition, blurred vision, mood changes, changes in activity, changes in cognitive and sensory capacity, allergic reactions, elevation of blood pressure and bradycardia. Rarely, it has been reported a worsening in patients with asthma. It has been reported infrequently an increase of the liver enzymes values during the treatment with Tramadol.

It can caused dependance showing the following symptoms: waving, anxiety, nervousness, insomnia, hipercinesis, shaking, and gastrointestinal symptoms.

If you detect any of the mentioned symptoms, or any other symptom not described in this leaflet, consult your doctor or pharmacist.

5. STORAGE OF TRAMADOL NORMON 100 mg/2 ml INJECTABLE SOLUTION:

Keep TRAMADOL NORMON 100 mg/2 ml INJECTABLE SOLUTION out of the reach and sight of children.

Store in the original package.

Expiry date: do not use TRAMADOL NORMON 100 mg/2 ml INJECTABLE SOLUTION after the date printed in the package.

6. INSTRUCTIONS FOR SANITARY STAFF:

Intravenous injection should be administered slowly during 2-3 minutes, or can also be administered by intravenous infusion.

Tramadol Hydrochloride presents physical incompatibility with the injectable solution of the following drugs: Diclofenac, Indomethacin, Phenylbutazone, Diazepam, Piroxicam, Salicylates. This should be taken into account when administering to polimedicated patients.