Nozinan® 25mg/ml Injection
(Levomepromazine Hydrochloride)

Is this leaflet hard to see or read?
Phone 01483 505515 for help
Read all of this leaflet carefully before you start receiving this medicine.
- Please keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor
- If you suffer from any side effects that get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor

In this leaflet:
1. What Nozinan Injection is and what it is used for
2. Before Nozinan Injection is given
3. How Nozinan Injection is given
4. Possible side effects
5. How to store Nozinan Injection
6. Further information

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

Nozinan Injection belongs to a group of medicines called phenothiazines. It is used for the relief of severe pain and as a sedative to relieve anxiety and distress associated with severe pain, particularly in terminally ill patients. This medicine is given by a healthcare professional either by injection into a muscle or vein, or slowly via a needle under the skin.

2. BEFORE NOZINAN INJECTION IS GIVEN

You MUST NOT be given Nozinan Injection if you have:
- an allergy (hypersensitivity) to levomepromazine hydrochloride or any of the other ingredients in the product (see Section 6 and end of Section 2)

Take special care with Nozinan Injection
Consult your doctor if you:
▲ have liver problems
▲ are elderly, frail or have heart disease as you may feel faint or light-headed when you are given the injection. (if you receive a large initial dose, you will have to stay in bed)
▲ suffer from slow or irregular heartbeats/palpitations (Torsades de Pointes) or have a family history of heart problems
▲ or someone else in your family have a history of blood clots, as medicines like these have been associated with formation of blood clots
▲ are diabetic or have been told that you have an increased risk of diabetes
▲ already know you have low levels of potassium, calcium or magnesium in your blood
▲ find it difficult, or are unable, to eat
▲ are an alcoholic

3. HOW NOZINAN INJECTION IS GIVEN

Your doctor will prescribe the appropriate dosage for your condition. The medicine will be given to you by a healthcare professional, either by injection into a muscle or vein or slowly via a needle under your skin.

Adults, including the elderly
- The usual dose is half to one vial by injection, although up to two vials may be used. This dose may be repeated every 6 to 8 hours if required

Alternatively a dose of up to 8 vials diluted with saline may be infused over 24 hours. Nozinan Tablets 25mg may be given instead of Nozinan Injection if oral therapy is more convenient.

Additional tests will be done by your doctor at the start of treatment, if you are being given Nozinan Injection for a long period of time, or if you are taking other medicines at the same time such as heart drugs, anti-depressants or drugs for mental health disorders. These tests might include an ECG (electrocardiogram) to check your heart is working normally and/or blood tests.

4. POSSIBLE SIDE EFFECTS

These include:
- medicines for the treatment of irregular heartbeats
- antidepressants and drugs for other mental health disorders (i.e. antipsychotics)
- desferrioxamine (for iron poisoning)
- adrenaline (epinephrine) in patients overdosed with antipsychotic drugs

Food and drink with Nozinan Injection
Avoid alcohol while you are having these injections.

Pregnancy and breast-feeding
If you are pregnant, planning to become pregnant or breast-feeding, ask your doctor or pharmacist before taking any medicine. The following symptoms may occur in newborn babies, of mothers that have used Nozinan Injection in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

Driving and using machines
Do not drive or operate machinery whilst receiving Nozinan Injections as it may make you feel drowsy, confused, dizzy or lightheaded.

Important information about some of the ingredients of Nozinan Injection
Sodium - this medicinal product is essentially ‘sodium-free’ as it contains less than 1mmol sodium (23mg) per millilitre.
Children
- If the injection is given to children, the dose will be calculated according to their weight; usually 0.35mg - 3.0mg/kg/day

If you are given more Nozinan Injection than you should
As this product will be given to you under medical supervision, it is unlikely that you will be given too much. However, speak to your doctor or nurse if you are worried. Symptoms of overdose include: drowsiness or loss of consciousness, low blood pressure, irregular heartbeats and hypothermia (abnormally low body temperature).

If a Nozinan Injection is missed
Contact your doctor or nurse as soon as you remember to arrange another appointment for your next injection.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Nozinan Injection can cause side effects, although not everybody gets them.

Allergic reaction - if following your injection you experience symptoms such as skin rash, swelling or breathing difficulties, inform your doctor immediately. This may be an indication that you are sensitive to the medicine and should not be given a repeat dose.

Frequent side effects include: sleepiness, weakness and dry mouth.

Tell your doctor IMMEDIATELY if you experience any of the following:
- dizziness, feeling faint or loss of alertness
- fever, ulceration of the mouth or throat, or sore throat
- stiffness, shaking (tremor) or slow movement
- low blood pressure, especially in elderly patients
- heart palpitations (usually rapid or irregular heartbeats)
- blood abnormalities
- jaundice (yellowing of the skin and eyes)
- constipation, which may become severe and stop food moving through the bowel
- heat stroke
- high temperature, sweating, pale complexion, difficulty in passing urine
- colicky abdominal pain with bloody diarrhoea
- skin irritation or burning due to sensitivity to sunlight
- unwanted and persistent erections
- Blood clots in the veins especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing. If you notice any of these symptoms seek medical advice immediately.

Other side effects include:
- high blood sugar (hyperglycaemia)

If any of these side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor
In elderly people with dementia, a small increase in the number of deaths has been reported for patients taking antipsychotics compared with those not receiving antipsychotics.

5. HOW NOZINAN INJECTION IS STORED

Keep out of the sight and reach of children. Protect from light. Do not use Nozinan Injection after the expiry date which is stated on the pack. Medicines should not be disposed of via wastewater or household waste. Your hospital pharmacist will dispose of any medicine no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Nozinan Injection contains
The active ingredient is levomepromazine hydrochloride (25mg/ml) per vial.
The other ingredients are ascorbic acid, sodium sulfite, sodium chloride and Water for injections (see end of Section 2 for further, important information on Sodium).

What Nozinan Injection looks like and contents of the pack
Nozinan Injection is a clear, colourless solution for injection. It is supplied in packs of 10 colourless glass vials.

Product procured from within the EU by the Parallel Product Authorisation Holder:
IMED Helathcare Ltd
New Road
Buncrana
Co Donegal
Ireland

Manufacturer:
Gruppo Lepetit Srl
Località Valcanello
03012 Anagni,
Italy
PL 40854/0029

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