

PACKAGE LEAFLET: INFORMATION FOR THE USER
Nozinan® 25mg/ml Solution for Injection/Infusion
levomepromazine hydrochloride

Is this leaflet hard to see or read? Phone 0118 211 4039 for help

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse 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 illness are the same as yours.
- If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Nozinan Injection is and what it is used for
2. What you need to know before Nozinan Injection is given
3. How Nozinan Injection is given
4. Possible side effects
5. How to store Nozinan Injection
6. Contents of the pack and other 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. WHAT YOU NEED TO KNOW BEFORE NOZINAN INJECTION IS GIVEN

Do not use Nozinan Injection if:

- X You are allergic (hypersensitivity) to levomepromazine hydrochloride or any of the other ingredients of Nozinan Injection (listed in section 6 below).
Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- X If you are taking any of the following medicines:
 - citalopram and escitalopram
 - hydroxyzine
 - piperazine
 - domperidone

Warnings and precautions

Talk to your doctor or nurse before Nozinan Injection is given if:

- You have liver or kidney problems
- You are an elderly patient with dementia
- You are elderly, frail, have heart disease or you have had problems with dizziness or feeling faint when going from a lying or sitting to a standing position due to low blood pressure, 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. You should not get up quickly and you should obtain assistance when necessary.

- You suffer from slow or irregular heartbeats/palpitations (torsades de pointes) or have a family history of heart problems
- You or someone else in your family have a history of blood clots, as medicines like these (antipsychotics) have been associated with formation of blood clots
- You have been told by your doctor that you might have a stroke or you have risk factors (e.g. if you smoke or have high blood pressure, or have an excessive amount of sugar, cholesterol or fat in the blood). This medicine should be used with caution as the risk of a stroke (cerebrovascular accident) may be increased.
- You are diabetic or have been told that you have an increased risk of diabetes. You will need to monitor your blood sugar levels very carefully.
- You already know you have low levels of potassium, calcium or magnesium in your blood
- You have constipation
- You find it difficult, or are unable, to eat
- You are an alcoholic
- You have ever had convulsions or epilepsy
- Your prostate (sperm-producing gland) has increased in size (prostate hypertrophy)
- You have an adrenal gland tumour (phaeochromocytoma)
- You have decreased thyroid hormone secretion condition (hypothyroidism)
- You have a muscle disease causing drooping eyelids, double vision, difficulty in speaking and swallowing and sometimes muscle weakness in the arms or legs (myasthenia gravis)

During the treatment

You must tell your doctor or nurse immediately if:

- You experience stiffness in your muscles, impaired consciousness and fever (see section 4).
- You have a fever, pallor, heavy sweating or any other sign of infection. In very rare cases, this medicine can cause a drop in your white blood cells which predisposes you to infection (see section 4).
- You have long-term constipation, as well as bloating and stomach pain, or a blocked intestine (Paralytic ileus) (see section 4).

Tests

Additional tests will be done by your doctor before and during treatment. This includes 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. Your doctor may carry out:

- blood tests to monitor your liver function.
- blood tests to check your white blood cells due to a potential side effect, a significant decrease in the number of certain white blood cells in the blood (agranulocytosis).
- an ECG (electrocardiogram) to check your heart is working normally, as certain medicines in the same family as NOZINAN (antipsychotics) can, in very rare cases, cause heart rhythm disorders (see section 4).

Other medicines and Nozinan Injection

Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other medicines, including those obtained without a prescription, as they may change the way Nozinan Injection works.

Do not use Nozinan Injection and tell your doctor if you are taking any of the following medicines (see section 2 'Do not use Nozinan Injection if'):

- citalopram and escitalopram – used to treat anxiety or depression

- hydroxyzine – used to treat the minor symptoms of anxiety, as premedication before general anaesthesia, in nettle rash and in the treatment of some kinds of insomnia
- piperazine – used to treat malaria, an illness caused by a parasite
- domperidone – used to treat nausea and vomiting

Before using Nozinan Injection, tell your doctor if you are taking any of the following medicines:

- medicines used for the treatment of Parkinson’s disease
- cabergoline, quinagolide – used to treat the production of excessive or abnormal amounts of milk
- medicines containing alcohol
- desferrioxamine – used to treat iron poisoning
- adrenaline (epinephrine) – used to treat patients overdosed with antipsychotic drugs
- medicines that can cause severe heart rhythm disorders (torsades de pointes):
 - antiarrhythmics used to treat irregular heartbeats (e.g. amiodarone, dronedarone, disopyramide, hydroquinidine, quinidine and sotalol)
 - medicines used to treat mental health disorders such as anti-depressants (e.g. amitriptyline, amitriptylinoxide and nortriptyline) and antipsychotics (e.g. other neuroleptics or lithium-containing medicines)
 - sedatives and medicines used to treat anxiety (e.g. barbiturates)
 - anti-parasitics used to treat diseases caused by parasites (e.g. chloroquine, halofantrine, hydroxychloroquine, lumefantrine and pentamidine)
 - antibiotics used to treat infections (e.g. erythromycin and spiramycin administered into a vein, and moxifloxacin)
 - mizolastine – used to treat an allergy
 - anti-cancer medicines used to treat cancer (e.g. toremifene, arsenic trioxide and vandetanib)
 - dolasetron administered into a vein – used in adults to treat or prevent nausea and vomiting induced by some treatments or surgery
 - vincamine administered into a vein – used to treat some minor neurological disorders related to ageing
 - diphemanil – used to treat gastric secretion disorders and excessive perspiration
 - prucalopride – used to treat constipation
 - mequitazine – used to treat allergic rhinitis or hives
 - methadone – used to treat addiction

Nozinan Injection with alcohol

Avoid alcohol while you are having these injections.

Fertility, pregnancy and breast-feeding

Pregnancy

Talk to your doctor or nurse before using this medicine:

- if you are a woman of childbearing potential and are not using effective contraception
- if you are pregnant, think you may be pregnant or are planning a pregnancy

This medicine will only be used during pregnancy on the advice of your doctor.

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.

Breast-feeding

This medicine is excreted into breast milk. Breast-feeding is not recommended for the duration of treatment with this medicine.

Fertility

The use of this medicine can result in an excessive amount of prolactin (the hormone which causes milk to be produced) in the blood. This may be associated with a lowering of fertility.

If you are pregnant, planning to become pregnant or breast-feeding, ask your doctor, nurse or pharmacist before taking any medicine.

Driving and using machines

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

Nozinan Injection contains

- **Sodium:** This medicine contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially 'sodium-free'.
- **Sulphites:** May rarely cause severe hypersensitivity reactions and bronchospasm.

3. HOW NOZINAN INJECTION IS GIVEN

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or nurse if you are not sure.

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 6-8 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.

Children

If the injection is given to children, the dose will be calculated according to their weight; usually 0.35-3.0mg/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, convulsions, low blood pressure, irregular heartbeats and hypothermia (abnormally low body temperature) and severe extrapyramidal dyskinesias (involuntary movements).

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, this medicine can cause side effects, although not everybody gets them.

Tell your doctor or nurse IMMEDIATELY if you notice any of the following serious side effects – you may need urgent medical treatment:

- You have an **allergic reaction**. Signs include: severe itching of the skin, with a red rash or raised lumps (hives), difficulty breathing or swallowing, swelling of the face, lips, tongue or throat. This may be an indication that you are sensitive to the medicine and should not be given a repeat dose.

Common (may affect up to 1 in 10 people)

- low blood pressure, especially in elderly patients or when you move suddenly from lying or sitting to a standing position
- heat stroke

Uncommon (may affect up to 1 in 100 people)

- stiffness, shaking (tremor) or slow movements
- you have a fit (seizure)
- blood abnormalities
- constipation, which may become severe and stop food moving through the bowel
- a significant decrease in the number of white blood cells, sometimes revealed by fever and breathing difficulties (agranulocytosis)

Rare (may affect up to 1 in 1,000 people)

- heart palpitations (usually rapid or irregular heartbeats)
- alteration of heart rhythm (called 'prolongation of QT interval' seen on ECG, electrical activity of the heart), which may, in exceptional cases, be life-threatening
- jaundice (yellowing of the skin and eyes)

Not known (frequency cannot be estimated from the available data)

- dizziness, feeling faint or loss of alertness
- 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.
- Neuroleptic malignant syndrome. Signs include: a high fever, sweating, pale complexion, stiff muscles, fast heart rate, fast breathing, difficulty passing urine and drowsiness or confusion. There may also be difficulty in walking and shaking or involuntary muscle movements. Rarely there may be rolling of the eyes. If these symptoms develop, please contact your doctor immediately. **See also section 2.**
- very severe inflammation of the intestine, which may cause localised destruction (necrosis), colicky abdominal pain with bloody diarrhoea
- skin irritation or burning due to sensitivity to sunlight
- unwanted, painful and persistent erections
- an illness where the removal of bile from the liver is blocked (cholestasis). Signs include jaundice, rash or fever, and the colour of your water (urine) becomes darker.
- you have discolouration of the skin or eyes, pain in the abdomen (stomach) or a bloated feeling, severe itching, pale or bloody stools, extreme weakness, nausea or loss of appetite. This could be caused by an infection or injury to the liver.
- tired, weak, confused, have muscles that ache, are stiff or do not work well. This may be due to low sodium levels in your blood.
- feeling unwell, confused and/or weak, feeling sick (nausea), loss of appetite, feeling irritable. This could be something called a syndrome of inappropriate antidiuretic secretion (SIADH).
- disease of the brain (Parkinson's disease) affecting movement (trembling, rigid posture, mask-like face, slow movements and a shuffling, unbalanced walk)
- uncontrollable twitching or jerking movements of the arms and legs (dyskinesia)
- decreased number of white blood cells (leukocytopenia), which may lead to serious infections

Other side effects include:

Very common (may affect more than 1 in 10 people)

- sleepiness
- dry mouth

Common (may affect up to 1 in 10 people)

- weakness

Not known (frequency cannot be estimated from the available data)

- lack of periods in women, increased breast size or breast growth in men, impotence, abnormal milk production
- high blood sugar (hyperglycaemia)
- a change in body temperature
- mood disorders, feeling anxious or confused
- weight gain
- vision problems including disorders affecting the ability of your eyes to adapt to see close up or far away (accommodation disorders), or brownish deposits in the eye that do not generally affect vision

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.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW NOZINAN INJECTION IS STORED

This medicine will be kept by your doctor or nurse in a safe place out of the sight and reach of children.

Do not have this medicine after the expiry date. This is stated in month and year on the carton and on the label after EXP. The expiry date refers to the last day of that month. If you are not sure when this is, check with your doctor or nurse.

Protect from light. You will not be asked to store your medicine. It will be brought to you ready to be given straight away.

Do not throw away any medicines via wastewater. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION**What Nozinan Injection contains**

The **active** ingredient is levomepromazine hydrochloride (25mg/ml) per vial.

The **other** ingredients are ascorbic acid, anhydrous sodium sulphite, sodium chloride and Water for injections

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.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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This leaflet was last revised in 06/2023