

**PACKAGE LEAFLET: INFORMATION FOR THE USER**  
**Nozinan® 25 mg/ml Solution for Injection/Infusion**  
*Levomepromazine Hydrochloride*

**Is this leaflet hard to see or read? Phone 01 403 5600 for help.**

**Read all of this leaflet carefully before you start taking 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**

1. What Nozinan is and what it is used for
2. What you need to know before Nozinan is given
3. How Nozinan is given
4. Possible side effects
5. How to store Nozinan
6. Contents of the pack and other information

**1. What Nozinan is and what it is used for**

Nozinan belongs to a group of medicines called phenothiazines.

Nozinan is used:

- In the treatment of schizophrenia and other mental disorders
- In 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 is given**

**Do not use this medicine and tell your doctor if:**

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

## Warnings and precautions

Talk to your doctor, pharmacist or nurse before receiving Nozinan if:

- You are pregnant or breast-feeding or think you might be pregnant.
- You have any liver, kidney, heart, urinary or prostate problems.
- Your prostate (sperm-producing gland) has increased in size (prostate hypertrophy).
- 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 get help when necessary.
- You have low levels of potassium, calcium or magnesium in your blood. Your doctor may do blood tests to check on these.
- You have ever had convulsions, epilepsy or Parkinson's disease.
- 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 have diabetes. You will need to monitor your blood sugar levels very carefully.
- You are elderly and suffer from dementia.
- You suffer from an increased pressure within the eye (glaucoma).
- You have a history of blood disorders (agranulocytosis).
- You or someone in your family have a history of blood clots, as medicines like these (antipsychotics) have been associated with formation of blood clots.
- You are taking any other medicines.
- You are an alcoholic.
- You have constipation.
- You have decreased thyroid hormone secretion condition (hypothyroidism).
- You have a heart disorder.
- You have an adrenal gland tumour (phaeochromocytoma).
- 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).
- You have heart palpitations. Very rarely, serious disturbances of the rhythm of the heart, may occur and a small number of patients have died suddenly on medicines of this type (see section 4).

## Tests

Before and during treatment your doctor may want to carry out some tests. These might include:

- 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).
- Blood tests to monitor your liver function.
- An ECG (electrocardiogram) to check your heart is working properly.

## Other medicines and Nozinan

Tell your doctor, nurse or pharmacist if you are taking or have recently taken or might take any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Nozinan can affect the way some other medicines work. Also some medicines can affect the way Nozinan works.

In particular, check with your doctor if you are taking any of the following:

- Medicines for indigestion and heartburn (antacids)
- Medicines used for high blood pressure such as guanethidine or clonidine
- Medicines to control your heartbeat such as disopyramide
- Medicines for Parkinson's disease such as levodopa
- Medicines used to treat the production of excessive or abnormal amounts of milk such as cabergoline or quinagolide
- Medicines for fits (epilepsy) such as phenobarbital
- Medicines to treat anxiety and help you sleep (sedatives, barbiturates)
- Medicines for depression
- Medicines used to calm emotional and mental problems
- Water tablets (diuretics)
- Anticholinergic medicines – including some medicines used for irritable bowel syndrome, asthma or incontinence
- Medicines containing lithium

## Nozinan with alcohol

Do not drink alcohol while you are being treated with Nozinan.

## Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor, nurse or pharmacist for advice before taking this medicine.

## 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 in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, slow or rapid heartbeat, abdominal bloating, constipation and difficulty 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.

### **Driving and using machines**

You may feel sleepy, disorientated or confused after having this medicine. If this happens, do not drive or use any tools or machines.

### **Nozinan contains**

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

## **3. How Nozinan is given**

Nozinan is normally given by a doctor or nurse. This is because it needs to be given as an injection into the muscle or by injection into the vein or directly under the skin.

#### *Adults:*

The usual daily dosage is 12.5 - 25 mg (0.5-1 ml) by injection into the muscle or by injection into the vein after dilution with an equal volume of normal saline immediately before use.

In cases of severe agitation, up to 50 mg (2 ml) may be used, repeated every six to eight hours.

Nozinan may also be administered over a 24 hour period via a syringe driver by an injection directly underneath the skin.

The required dose of Nozinan (25- 200 mg per day) should be diluted with the calculated volume of normal saline. Diamorphine hydrochloride is compatible with this solution and may be added if greater analgesia is required.

Patients should remain lying down for at least one hour after injection due to the risk of hypotension.

### **If you are given more Nozinan than you should**

It is highly unlikely that your doctor or nurse will give you too much medicine. Your doctor and nurse will monitor your progress, and check the medicine you are given. However speak to your doctor or nurse if you are worried.

Having too much Nozinan can cause the following symptoms:

- drowsiness or loss of consciousness
- low blood pressure
- irregular heartbeats
- hypothermia (abnormally low body temperature).

If you start to get any of these symptoms tell your doctor or nurse straight away.

#### **If you miss a dose of Nozinan**

Contact your doctor or nurse as soon as you remember to arrange another appointment for your next injection.

#### **If you stop having Nozinan**

Keep having Nozinan until your doctor tells you to stop. If you suddenly stop having Nozinan your illness may come back and you may have other side effects.

#### **4. Possible side effects**

Like all medicines, Nozinan 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, rash, difficulty breathing or swallowing, swelling of the face, lips, tongue or throat.

If you suffer constipation or abdominal cramps whilst taking this medicine you should contact your doctor immediately. This could be a symptom of paralytic ileus.

#### **Other side effects include:**

- Dizziness, feeling faint, less alert or confused and delirious
- Fever, ulceration of your mouth or throat or a sore throat
- Dry mouth
- Drowsiness or feeling anxious and notice a change in your mood
- Inability to control certain muscles in your body, this may affect your tongue, mouth or jaw, arms and legs. Signs can include uncontrollable twitching or jerking movements of the arms and legs (dyskinesia)
- Urge to move about constantly, this may occur particularly after large starting doses
- Low blood pressure, especially in elderly patients
- Heart palpitations (unusually rapid or irregular heartbeats) or a weak pulse
- Chest pain, numbness or a tingling sensation
- Feeling particularly hot or cold
- 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
- Discolouration or irritation of the skin
- Stomach upset, diarrhoea, constipation or urinary retention
- Weight gain
- Intolerance to glucose, this could be a sign of hyperglycaemia. Signs can include feeling more thirsty than usual and having to urinate more often
- Fits (seizures)
- Muscle stiffness, trembling, rigid posture, mask-like face, slow movements and a shuffling, unbalanced walk. These could be symptoms of Parkinson's disease
- Yellow discolouration of the skin or eyes (jaundice), 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 injury to the liver

- Cholestasis, an illness where the removal of bile from the liver is blocked. Signs include jaundice, rash or fever, and the colour of your urine becomes darker
- Feeling unwell, confused and/or weak, feel sick (nausea), loss of appetite, feel irritable. This could be something called a syndrome of inappropriate anti-diuretic hormone secretion (SIADH)
- Feeling tired, weak, confused and have muscles that ache, are stiff or do not work well. This may be due to low sodium levels in your blood
- Hormonal imbalance – this may cause enlarged breasts and impotence or persistent erections in men, milk production in non breast-feeding women and loss of menstrual periods
- Sensitivity to sunlight. If this occurs you should avoid sun-lamps and direct sunlight. You may be advised to wear a sunscreen
- Thrombocytopenia which is a decrease in the number of platelets (cells in the blood that help with clotting) found in a blood test, which can lead to bleeding and bruising (thrombocytopenic purpura).
- Eosinophilia which is an increase in the number of eosinophils (a type of white blood cells) found in a blood test.

Rarely a group of side effects may occur together: high fever with very stiff muscles, sweating, palpitations, breathing problems and confusion or drowsiness.

### **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 HPRC Pharmacovigilance, Website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Nozinan**

Do not store above 25°C. Keep the ampoule in the outer carton to protect from light. Discoloured solution must not be used. Diluted solutions are for single use and should be used immediately after preparation.

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

Do not use this medicine after the expiry date which is stated on the bottle ampoule and carton after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

### **6. Contents of the pack and other information What Nozinan contains**

The active ingredient is levomepromazine hydrochloride. Each 1 ml of solution contains 25 mg levomepromazine hydrochloride.

The other ingredients include ascorbic acid (E300), sodium sulphite anhydrous (E221), sodium chloride and water.

**What Nozinan looks like and contents of the pack**

Nozinan Injection/Infusion is a clear, bright, pale yellow solution. It is available in outer cartons of 10 glass ampoules. The 2 ml ampoule contains 1 ml of solution.

**Marketing Authorisation Holder and Manufacturer**

Marketing Authorisation Holder

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