PACKAGE LEAFLET: INFORMATION FOR THE USER

Nozinan® 25mg Tablets
levomepromazine maleate

SANOFI

Is this leaflet hard to see or read?
Phone 0845 372 7101 for help

Read all of this leaflet carefully before you start taking this medicine.
- Please keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others; it may harm them, even if their symptoms are the same as yours.
- 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 Tablets are and what they are used for
2. Before you take Nozinan Tablets
3. How to take Nozinan Tablets
4. Possible side effects
5. How to store Nozinan Tablets
6. Further information

1. What Nozinan Tablets are and what they are used for

Nozinan Tablets belong to a group of medicines called phenothiazines and are used for:
• schizophrenia
• the relief of pain and accompanying distress in terminally ill patients.

2. Before you take Nozinan Tablets

Do NOT take Nozinan Tablets if:
• You are allergic (hypersensitive) to levomepromazine maleate or any of the other ingredients in the product (see Section 6).

Take special care with Nozinan Tablets
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 take the tablets (if you have 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
• suffer from dementia and are elderly
• have been told by your doctor that you might have a stroke
• are diabetic or have been told you have an increased risk of having 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
• have epilepsy.

Additional tests will be done by your doctor at the start of treatment if you are taking Nozinan Tablets for a long period of time, or if you are taking other medicines at the same time such as heart drugs, antidepressants or drugs for mental health disorders.

These tests might include an ECG (electrocardiogram) to check your heart is working normally and/or blood tests. If you have to go to the dentist or hospital for any reason, tell them that you are taking Nozinan Tablets.

3. How to take Nozinan Tablets

Always take this medicine exactly as your doctor has told you; you should check with him/her if you are not sure. The tablets should be swallowed whole with a glass of water.

Schizophrenia
Adults - the initial dose is usually 1 to 2 tablets a day, divided into three doses. If you are confined to bed, the initial dose may be 4 to 8 tablets a day, divided into three doses. These doses may be increased in small steps until a suitable dose is found for you.

Elderly - your doctor will decide whether these tablets are appropriate for you and will tell you how many to take.

Children - will normally be given no more than 1 ½ tablets a day.

Pain management
Adults and Elderly – ½ to 2 tablets every four to eight hours; the dose may be varied until a suitable dose is found for you.

Children - these tablets are NOT recommended for children for treating pain.

If you take more Nozinan Tablets than you should
If you, or a child, accidentally swallow too many tablets, contact your doctor or nearest hospital casualty department immediately.

Symptoms of overdose include: drowsiness or loss of consciousness, convulsions, low blood pressure, irregular heartbeats, hyperthermia (abnormally low body temperature) and severe extrapyramidal dyskinesias (involuntary movements).

4. Possible side effects

Consult your doctor if you:
• medicines for the treatment of irregular heartbeats
• antidepressants such as amitriptyline and amitriptyline maleate and drugs for other mental health disorders (i.e. antipsychotics)
• desferrioxamine (for iron poisoning)
• adrenaline (epinephrine) in patients overdosed with antidepressive drugs.

Taking with food and drink
Avoid alcohol while you are taking these tablets.

Pregnancy and breast-feeding
If you are pregnant, planning to become pregnant or breast-feeding, ask your doctor or pharmacist before taking Nozinan Tablets or any other medicine. The following symptoms may occur in newborn babies, of mothers that have used Nozinan Tablets 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 if taking Nozinan Tablets as they may make you feel drowsy, confused, dizzy or lightheaded.

5. How to store Nozinan Tablets

Store Nozinan Tablets in a tin. Keep the tin tight after removing the tablets. Store Nozinan Tablets below 25°C. Do not freeze. Do not use after the expiry date. 

6. Further information

Consult your doctor if you:
• already know you have low levels of potassium, calcium or magnesium in your blood
• are diabetic or have been told you have an increased risk of having diabetes
• have liver problems
• have blood clots, as medicines like these have been associated with formation of blood clots
• 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
• have been told by your doctor that you might have a stroke
• are diabetic or have been told you have an increased risk of having 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
• have epilepsy.

Additional tests will be done by your doctor at the start of treatment if you are taking Nozinan Tablets for a long period of time, or if you are taking other medicines at the same time such as heart drugs, antidepressants or drugs for mental health disorders.

These tests might include an ECG (electrocardiogram) to check your heart is working normally and/or blood tests. If you have to go to the dentist or hospital for any reason, tell them that you are taking Nozinan Tablets.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including those obtained without a prescription, as they may change the way Nozinan Tablets work. These include:
• medicines for the treatment of irregular heartbeats
• antidepressants such as amitriptyline and amitriptyline maleate and drugs for other mental health disorders (i.e. antipsychotics)
• desferrioxamine (for iron poisoning)
• adrenaline (epinephrine) in patients overdosed with antidepressive drugs.

Precautions
• You should avoid driving or operating machinery if you feel drowsy, confused, dizzy or lightheaded.
• Do not drink alcohol while you are taking these tablets.

Adverse Reactions
• Tachycardia (fast heart rate), hypotension (low blood pressure), tinnitus (ringing in the ears), hypothermia (abnormally low body temperature), agitation, diarrhoea, sweating, palpitations (Torsades de Pointes), abnormal movements.

Possible side effects
Nozinan Tablets may cause side effects which usually improve as your treatment continues. Side effects include:
• drowsiness or loss of consciousness, convulsions, low blood pressure, irregular heartbeats, hyperthermia (abnormally low body temperature) and severe extrapyramidal dyskinesias (involuntary movements).

If you experience any side effect which concerns you, or if the side effects persist or become severe, consult your doctor.

7. Further information

Consult your doctor if you:
• have epilepsy.

Additional tests will be done by your doctor at the start of treatment if you are taking Nozinan Tablets for a long period of time, or if you are taking other medicines at the same time such as heart drugs, antidepressants or drugs for mental health disorders.

These tests might include an ECG (electrocardiogram) to check your heart is working normally and/or blood tests. If you have to go to the dentist or hospital for any reason, tell them that you are taking Nozinan Tablets.

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Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including those obtained without a prescription, as they may change the way Nozinan Tablets work. These include:
• medicines for the treatment of irregular heartbeats
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• You should avoid driving or operating machinery if you feel drowsy, confused, dizzy or lightheaded.
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Adverse Reactions
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If you forget to take Nozinan Tablets
If you miss a dose, just take your tablets as soon as you remember then carry on as before. Do not take a double dose to make up for the forgotten one. 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 Tablets can cause side effects, although not everybody gets them.

STOP taking the tablets and SEEK medical help immediately if you have any of the following allergic reactions:
- difficulty breathing or swallowing, swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised lumps.

Very common: may affect more than 1 in 10 people:
- sleepiness
- dry mouth
Common: may affect up to 1 in 10 people:
- weakness

Tell your doctor IMMEDIATELY if you experience any of the following:
Common: may affect up to 1 in 10 people:
- low blood pressure, especially in elderly patients
- heat stroke
- alteration of heart rhythm (called ‘prolongation of QT interval’ seen on ECG, electrical activity of the heart)
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
Rare: may affect up to 1 in 1,000 people:
- heart palpitations (usually rapid or irregular heartbeats)
- 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
- a serious but rare side effect is neuroleptic malignant syndrome. Signs of this include a high fever, sweating, stiff muscles, fast heart rate, fast breathing and drowsiness or confusion. There may also be difficulty in walking and shaking or involuntarily muscle movements. Rarely there may be rolling of the eyes. If these symptoms develop please contact your doctor immediately.
- high temperature, sweating, pale complexion, difficulty passing urine
- colicky abdominal pain with bloody diarrhoea
- skin irritation or burning due to sensitivity to sunlight
- unwanted 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 urine (urine) becomes darker
- you have discoloration 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)

Other side effects include:
Not known: frequency cannot be estimated from the available data:
- high blood sugar (hyperglycaemia)
- feeling confused
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.

If any of these side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

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 to store Nozinan Tablets
Keep out of the reach and sight of children.
Store in the original container below 25°C and protect from light.
Do not use the product after the expiry date ‘EXP’ (last day of the month stated) printed on the blister and carton.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of any medicine no longer required. These measures will help to protect the environment.

6. Further information
What Nozinan Tablets contain
The active ingredient is levomepromazine maleate, 25mg per tablet.
The other ingredients are potato starch, calcium hydrogen phosphate, magnesium stearate and sodium lauryl sulfate.

What Nozinan Tablets look like and contents of the pack
The tablets are round, greyish-white cream, with one side marked ‘NOZINAN 25’ and a break line on the other side. They are supplied in blister packs containing 84 tablets or plastic bottles containing 500 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
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