

Nozinan[®] Tablets

levomepromazine maleate

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about Nozinan.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits he expects it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Nozinan is used for

Nozinan is a type of neuroleptic used in both psychiatry and severe pain.

It is not known exactly how Nozinan has these effects.

The effect of Nozinan is to relieve severe pain without making you feel sick or vomit. It relieves the anxiety and distress associated with severe pain. Nozinan can also be used to treat schizophrenia.

Your doctor, however, may prescribe Nozinan for another purpose.

Ask your doctor if you have any questions about why it has been prescribed for you.

This medicine is only available with a doctor's prescription.

There is no evidence that this medicine is addictive.

Before you take it

When you must not take it

Do not take Nozinan if you have:

- liver disease
- heart disease
- urinary or prostate problems
- increased pressure in the eye (glaucoma)
- a history of a lack of white blood cells (agranulocytosis)

Do not take Nozinan if you are allergic to it or any of the ingredients listed at the end of this leaflet.

Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

Do not take it if you are breastfeeding or planning to breastfeed.

Nozinan may pass into breast milk and there is a possibility your baby may be affected.

Do not take it after the expiry date (EXP) printed on the pack.

If you take it after the expiry date has passed, it may not work as well.

Do not take it if the packaging is damaged or shows signs of tampering.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to:

- any of the ingredients listed at the end of this leaflet
- any other substances, such as foods, preservatives or dyes.

Tell your doctor or pharmacist if you are pregnant or intend to become pregnant.

Like most medicines of this kind, Nozinan is not recommended to be used during pregnancy. Your doctor or pharmacist will discuss the risks and benefits of taking it if you are pregnant.

Tell your doctor or pharmacist if you are breastfeeding or planning to breastfeed.

It is not known whether Nozinan passes into breast milk. Your doctor or pharmacist will discuss the risks and benefits of taking it if you are breastfeeding or planning to breastfeed.

Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:

- heart disease
- liver disease
- kidney disease
- an underactive thyroid gland, causing a decrease in metabolism
- pheochromocytoma - a rare tumour of the adrenal gland which sits near the kidneys.
- disease of the muscles causing drooping eyelids, double vision, difficulty in speaking and swallowing and sometimes muscle weakness in the arms or legs (myasthenia gravis)
- slow or irregular heartbeats or palpitations or have a family history of these
- low levels of potassium, calcium or magnesium in your blood
- blood clots
- diabetes or risk factors for developing diabetes
- Parkinson's disease
- dementia

- epilepsy
- if you have a high consumption of alcohol

Tell your doctor or pharmacist if you plan to have surgery.

If you have not told your doctor or pharmacist about any of the above, tell them before you take Nozinan.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food store.

Some medicines may interfere with Nozinan. These include:

- medicines for Parkinson's disease such as levodopa
- other antipsychotics
- sedatives (medicines that help you sleep)
- hypnotics (medicines that help you relax or reduce stress)
- medicines that affect heart rhythm (such as disopyramide, amiodarone, beta-blockers, verapamil, diltiazem)
- medicines that cause low levels of potassium in your blood (such as diuretics, stimulant laxatives)
- desferrioxamine (removes excess iron from the body)
- adrenaline (sends more oxygen to the brain and muscles)
- medicines metabolised by CYP2D6 (such as amitriptyline or amitriptylinoxide)
- medicines that lower blood pressure (such as guanethidine)
- some cough and cold preparations or eye drops containing atropine and atropine-like substances
- medicines used to treat mood swings and depression, including lithium

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking Nozinan.

How to take it

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How much to take

Your doctor or pharmacist will tell you how much Nozinan you will need to take each day. This depends on your condition.

Adult dose:

The usual recommended dose for adults with terminal pain is half to two Nozinan 25 mg tablets every 4 to 8 hours.

The usual recommended daily dose for adults with schizophrenia is half to two Nozinan 25mg tablets. This is usually divided into three doses.

Your doctor may have prescribed a different dose.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Nozinan may not work as well and your problem may not improve.

How to take it

Swallow the tablets whole with a full glass of water or other liquid.

When to take it

Take Nozinan tablets every 4 to 8 hours irrespective of meals, or as prescribed by your doctor.

If you are not sure when to take it, ask your doctor or pharmacist.

How long to take it

Continue taking the tablets until your doctor tells you to stop.

Ask your doctor or pharmacist if you are not sure how long to take the medicine for.

If you forget to take it

Do not try to make up for missed doses by taking more than one dose at a time.

This may increase the chance of getting an unwanted side effect.

If it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to.

Do not take a double dose to make up for the dose you have missed.

If there is still a long time to go before your next dose, take it as soon as you remember, and then go back to taking it as you would normally.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for hints.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (New Zealand 0800 POISON or 0800 764766), or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much Nozinan.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too many Nozinan tablets, you will probably feel very sleepy or dizzy, you may faint or your heartbeat may become irregular.

While you are taking it

Things you must do

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Nozinan.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Nozinan.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking this medicine.

Things you must not do

Do not take more than the recommended dose unless your doctor tells you to.

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not use this medicine to treat any other complaints unless your doctor tells you to.

Do not stop taking Nozinan, or lower the dosage, without checking with your doctor.

Your doctor may want you to gradually reduce the amount you are using before stopping completely.

Do not stop taking your tablets because you are feeling better, unless advised by your doctor.

Things to be careful of

If you feel light-headed, dizzy or faint, get up slowly when getting out of bed or standing up.

Be careful driving or operating machinery until you know how Nozinan affects you.

It may cause dizziness or light-headedness in some people, especially after the first dose. Make sure you know how you react to it before you drive a car, operate machinery, or do anything else that could be dangerous if you feel dizzy.

Be careful if you are over 65 and unwell or taking other medicines. Some people may experience side effects such as drowsiness, confusion, dizziness and unsteadiness, which may increase the risk of a fall.

The effects of alcohol could be made worse while taking Nozinan. Avoid alcohol while taking Nozinan.

Side effects

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits he expects it will have for you.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Nozinan. It helps most people with severe pain or schizophrenia, but it may have unwanted side effects in a few people.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- drowsiness
- weakness
- dry mouth

These are mild side effects of this medicine and usually short-lived.

Tell your doctor or pharmacist immediately if you notice any of the following:

- dizziness, feeling faint or loss of alertness
- skin irritation or rash especially after going out into the sun, which may result in burning
- fever, ulcers in the mouth or throat, sore throat or any other infection
- tremors or shaking, muscle stiffness
- constipation, which may become severe and stop food moving through the bowel
- unwanted or persistent erections
- irregular or fast heart beat
- symptoms of high blood sugar levels such as excessive thirst, increased appetite with weight loss, feeling tired, passing large amounts of urine
- symptoms of jaundice such as yellowing of the skin and/or eyes
- feeling particularly hot or cold

- hormone imbalance which may cause breast enlargement and impotence in men or unusual secretion of breast milk in non-breastfeeding women, loss of menstrual periods and frigidity
- 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
- feeling unwell, confused and/or weak, feeling sick (nausea), loss of appetite, feeling irritable. This could be something called a syndrome of inappropriate anti-diuretic hormone secretion (SIADH)
- feelings of confusion, indifference or nervousness
- mood changes
- inability to control movement of certain muscles in your body
- restlessness or difficulty sitting still

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- high temperature, sweating, pale complexion, difficulty in passing urine
- convulsions, fits or seizures
- pain in the stomach with severe, colicky stomach pain with bloating, cramps, vomiting, bloody diarrhoea
- sudden severe headache, loss of vision and/or coordination, shortness of breath, chest pain, numbness or swelling in the arms and legs

These may be serious side effects of Nozinan. You may need urgent medical attention. Serious side effects are uncommon.

If any of the following happen, stop taking this medicine and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- hives
- fainting

- **yellowing of the skin and eyes (jaundice)**

These are very serious side effects. If you have them, you may have had a serious allergic reaction to Nozinan. You may need urgent medical attention or hospitalisation.

These side effects are very rare.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may occur in some consumers.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

After taking it

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

Storage

Keep your tablets in the blister pack, inside the box in which they came until it is time to take them.

If you take the tablets out of the box or the blister pack they may not keep well.

Keep the medicine in a cool, dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom, near a sink, or on a windowsill.

Do not leave it in the car.

Heat and damp can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor or pharmacist tells you to stop taking Nozinan, or the medicine has passed its expiry date, ask your pharmacist what to do with any that are left over.

Return any unused medicine to your pharmacist.

Product description

What it looks like

Nozinan is available in two strengths of tablets:

Nozinan 25 mg - white, rounded faced, round, breakable tablet, marked "L 25"

Nozinan 100 mg - white, rounded faced, round, breakable tablet, marked "L 100".

The 25 mg strength is available in boxes of 100 tablets.

The 100 mg strength is available in boxes of 100 tablets.

Ingredients

Active Ingredient:

Nozinan 25 mg – 25 mg
levomepromazine maleate per tablet
Nozinan 100 mg – 100 mg
levomepromazine maleate per tablet.

Inactive Ingredients:

The 25 mg tablets also contain:

- potato starch
- calcium hydrogen phosphate dihydrate
- sodium laurilsulfate
- magnesium stearate
- polyvinyl acetate
- macrogol 6000.

The 100 mg tablets also contain:

- potato starch
- calcium carbonate
- sodium laurilsulfate
- stearic acid
- polyvinyl acetate
- macrogol 6000.

Nozinan does not contain gluten, sucrose, lactose, tartrazine or any other azo dyes.

Manufacturer/Sponsor

sanofi –aventis new zealand limited
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