

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986
The medicine is dispensed with a doctor's prescription only

Nozinan 25 mg

Nozinan 100 mg



Active ingredient: Nozinan 25 mg, each film-coated tablet contains Levomepromazine 25 mg

Nozinan 100 mg, each film-coated tablet contains Levomepromazine 100 mg

For a list of inactive ingredients, see section 6.

Read this leaflet carefully in its entirety before using the medicine.

This medicine is not intended for use in children.

Keep this leaflet; you may need to read it again.

This leaflet contains concise information about the medicine.

This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

If a side effect worsens or if a side effect not mentioned in this leaflet occurs, please refer to a doctor or pharmacist. If you have further questions, refer to the doctor or pharmacist.

1. WHAT IS THE MEDICINE INTENDED FOR?

Nozinan belongs to a group of neuroleptic preparations and is intended for the treatment of certain psychotic disorders.

Therapeutic group: Antipsychotic preparation.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you have a known sensitivity to levomepromazine or to any of the ingredients of the medicine (see section 6 for the full list of ingredients).
- you are suffering from, or are at risk of glaucoma (an eye disease in which the increased pressure of fluids in the eye may impair vision).
- you are suffering from problems in passing urine.
- you are suffering, or have suffered from a significant drop in granulocytes (a type of white blood cells) in the blood.
- you are suffering from an allergy to wheat (other than celiac disease), since the medicine contains wheat starch.
- you are taking medicines which contain:
 - * cabergoline or quinagolide (medicines to treat abnormal milk secretion), as well as
 - * dronedarone (to treat heart rhythm disorders),
 - * mequitazine (to treat allergies).
- do not use if you suffer from certain severe cardiac diseases, in particular severe ischemic cardiac disease or heart failure.

Special warnings regarding use of the medicine

If you have fever, with or without signs of infection (sore throat, etc.), paleness or increased sweating, refer to the doctor or emergency room immediately.

Stop treatment and refer to the doctor immediately if muscle stiffness and impaired consciousness, accompanied by unexplained fever, occur.

Before starting treatment with Nozinan it is recommended that an ECG test be done (this test is recommended before administration of neuroleptic medicines such as Nozinan).

Refer to the doctor as soon as possible if you are suffering from prolonged constipation or severe flatulence and abdominal pains. This medicine can cause intestinal obstruction.

Exercise caution in patients with risk factors for stroke.

In very rare cases, this medicine may also cause severe inflammation of the intestine that can progress and cause organ tissue necrosis.

Exercise caution in elderly patients, who are particularly sensitive to the side effects of lowered blood pressure, and in elderly patients suffering from dementia.

Exercise caution if you or your family member are suffering or have suffered in the past from blood clotting problems, as taking antipsychotic medicines is associated with formation of blood clots.

The medicine contains lactose and is therefore not recommended for those suffering from galactosemia, from problems absorbing glucose and galactose or from lactase deficiency.

The medicine can be taken if you suffer from celiac disease. Wheat starch can contain gluten, but only in negligible quantities and is therefore considered safe for celiac patients.

Avoid switching abruptly from a lying/sitting position to standing to prevent dizziness and, in extreme cases, fainting.

Use of this medicine may cause blurred vision.

If you are about to undergo surgery (including dental) or any procedure involving anesthesia, tell the anesthesiologist that you are taking this medicine.

Take care not to get overheated during physical activity, in hot weather and in a hot shower (for fear of heat stroke). In addition take care not to get cold in cold weather (for fear of hypothermia).

Nozinan may lower the epileptogenic threshold; therefore, patients with epilepsy should take the medicine with caution.

Before treatment with the medicine, inform the doctor if you are suffering from:

- heart problem
- impaired function of the eyes
- impaired function of the blood system (e.g., coagulation, etc.) and/or the bone marrow
- Reye's syndrome
- dementia
- impaired function of the liver or kidney
- fits (in the past or recently), or epilepsy
- enlargement of the prostate gland
- constipation
- Parkinson's disease
- hypertension
- alcoholism
- diabetes or risk factors for diabetes

If you are taking or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

Do not use Nozinan together with medicines that contain:

cabergoline or quinagolide (for treatment of abnormal milk secretion), dronedarone (to treat heart rhythm disorders), mequitazine (to treat allergies).

Avoid taking Nozinan if you are already taking:

- antibiotics (medicines to treat infections), such as erythromycin or intravenous spiramycin and moxifloxacin
- mizolastine (antiallergic)
- anticancer medicines (medicines to treat cancer, such as toremifen or arsenic compounds)
- bepridil (if you are suffering from chest pain as a result of a heart disease)
- cisapride (a medicine for treating reflux of food and acids to esophagus)
- intravenous dolasetron (a medicine given to adults to treat or prevent nausea and vomiting caused by certain treatments or surgery)
- intravenous vincamine (a medicine for treatment of certain neurological disorders associated with aging)
- diphemanil (a medicine to treat disorders of the digestive system and increased sweating)
- medicines to treat Parkinson's disease
- medicines which contain alcohol
- medicines which may cause severe cardiac rhythm disorders:
 - medicines to treat rapid or irregular heart rate, such as amiodarone, disopyramide, dofetilide, hydroquinidine, ibutilide, quinidine and sotalol (antiarrhythmics)
 - medicines to treat certain psychiatric disorders, such as amisulpride, chlorpromazine, cyamemazine, droperidol, fluphenazine, pericyazine, haloperidol, pimozide, pipamperone, sertindole, sulpiride, sultopride, tiapride, flupentixol, zuclopentixol (neuroleptics)
 - medicines to treat diseases caused by parasites, such as halofantrine, pentamidine, lumefantrine
 - methadone (a medicine to treat addiction)
 - citalopram, escitalopram (medicines to treat depression and anxiety)
- levodopa

Be cautious about taking Nozinan if you are already taking:

- atropine or agents acting like atropine (e.g., antidepressants, antihistamines, anticholinergics).
- nitrates, nitrites and similar medicines.
- medicines which cause a reduction in potassium (e.g., hypokalemic diuretics, laxatives, glucocorticosteroids).
- medicines which affect the central nervous system (e.g., lithium, sedatives, hypnotics, antiepileptics, surgical anesthetics and narcotic analgesics).
- antihypertensives.
- topical medicines for the digestive system – salts, antacids containing magnesium oxide or hydroxide, aluminium oxide or hydroxide, calcium oxide or hydroxide – wait at least two hours between taking these medicines and Nozinan.

Use of the medicine and food:

Swallow the tablets whole with a glass of water, in the evening before going to sleep or three times a day with food.

Use of the medicine and alcohol consumption:

Do not drink wines or alcoholic beverages during the course of treatment with the medicine.

Pregnancy and breastfeeding:

If you are pregnant, planning to become pregnant, breastfeeding or planning to breastfeed, consult a doctor

before using the medicine.

The following symptoms may occur in babies whose mothers took Nozinan during the last three months of pregnancy: tremor, muscle stiffness or weakness, sleepiness, agitation, difficulties breathing and feeding. If your baby develops any of these symptoms, contact the doctor.

If you discover that you are pregnant, contact the doctor who will determine whether to continue the treatment with Nozinan.

Use the medicine only if the possible benefit to the patient outweighs the potential harm to the fetus.

Breastfeeding is not recommended while using the medicine. Refer to the doctor before starting to use the medicine.

Driving and use of machines:

Do not drive or use machines during treatment with the medicine, as it may cause drowsiness, confusion or dizziness.

Important information regarding some of the ingredients of the medicine:

The preparation contains lactose and is therefore not recommended for those suffering from galactosemia, problems absorbing glucose and galactose or from lactase deficiency.

The medicine can be taken if you are suffering from celiac disease. Wheat starch can contain gluten, but only in negligible quantities and is therefore considered safe for celiac patients.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions.

Check with the doctor or pharmacist if you are not sure. The dosage and treatment regimen will be determined by the doctor only.

Do not exceed the recommended dose.

At the beginning of treatment, the patient should lie down for about one hour after taking the medicine.

Avoid switching abruptly from a lying/sitting position to standing to prevent dizziness and in extreme cases, fainting.

Wait an interval of at least two hours between taking this medicine and taking laxatives, antacids.

Tests and follow up

Your doctor will send you for additional tests at the beginning of treatment, when you take Nozinan for a long time or if you are concomitantly taking other medicines with Nozinan, such as heart medicines, antidepressants or medicines for emotional problems. These tests may include ECG (electrocardiogram) to test for normal activity of the heart and/or blood tests.

If you are due to undergo surgery (including dental) or any other procedure which involves anesthesia, inform the anaesthesiologist that you are taking this medicine.

If you accidentally took a higher dosage, immediately refer to a doctor or proceed to a hospital emergency room. Symptoms of overdose include: seizures, Parkinson's syndrome and coma. Sleepiness or loss of consciousness, low blood pressure, irregular heart rate, low body temperature and involuntary movements.

If you took an overdose or if a child has accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine: If you forgot to take this medicine, take the dose when you remember and continue as usual. Do not take a double dose to compensate for a missed dose. Adhere to the treatment regimen recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor or pharmacist.

If you stop taking the medicine

Do not stop taking the medicine unless the doctor has instructed you to do so. Refer to the doctor before stopping treatment.

- Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, ask the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Nozinan may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Discontinue use and refer to the doctor immediately if the following occur:

- **Muscle stiffness and impaired consciousness, accompanied by unexplained fever.**
- **Fever, with or without signs of infection (sore throat, etc.), paleness or increased sweating.**

Refer to the doctor as soon as possible if you are suffering from prolonged constipation or severe flatulence and abdominal pains. This medicine can, in certain cases, cause intestinal obstruction.

Refer to the doctor immediately if you experience symptoms of thrombosis, especially in the legs. The symptoms include: swelling, pain and redness in the legs. The blood clot may pass through the blood vessels to the lungs and cause chest pain and difficulties breathing.

The following side effects may occur:

- Dizzy feeling when switching abruptly from a lying/sitting position to standing
- Dry mouth, difficulties passing urine, constipation, intestinal obstruction
- Vision problems, including the eye's ability to adapt from distance vision to close vision.
- Drowsiness, anxiety, mood changes
- Tremor, stiff and/or abnormal movements
- Impotence, sexual frigidity
- Weight gain
- Absence of menstrual period, breast swelling, abnormal secretion of breast milk
- Changes in blood sugar level
- Change in body temperature

Rare side effects:

- Heart rate disturbances, which can cause death in extreme cases
- Abnormal laboratory tests results (positive results for certain antibodies)
- Allergic skin reaction, exaggerated skin reaction upon exposure to the sun or UV rays
- A liver disease with yellowing of the skin and eyes

Rarer side effects:

- Severe inflammation of the intestine that can progress and cause organ tissue necrosis

Rarest effects:

- Significant reduction in the number of certain white blood cells, which may cause severe infections (granulocytes)
- Prolonged, painful erection
- Brown deposits in the eye, generally with no effect on vision

Unknown frequency:

Withdrawal syndrome in babies whose mothers took the preparation during the third trimester of pregnancy (last 3 months of pregnancy) (see Pregnancy section).

Additional reported side effects: seizures, confusion, hallucination, liver injury.

Decrease in blood sodium levels, syndrome of inappropriate antidiuretic hormone secretion (SIADH).

If any of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, you must consult with the doctor.

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.

Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of the indicated month.

Store at a temperature below 25°C. Store in a dark place.

6. FURTHER INFORMATION

In addition to the active ingredient, Nozinan 25 mg tablet also contains: Lactose monohydrate (122.5 mg), wheat starch (58.7 mg), hydrated colloidal silica, dextrin, magnesium stearate, hypromellose, macrogol 20000.

In addition to the active ingredient, Nozinan 100 mg tablet also contains: Lactose monohydrate (205.0 mg), wheat starch (90.0 mg), hydrated colloidal silica, dextrin, magnesium stearate, hypromellose, macrogol 20000.

What does the medicine look like and what are the contents of the package:

The tablets are packaged in a blister.

Nozinan 25 mg tablets are: film-coated, round, cream-white colored, with Nozinan 25 imprinted on one side and with a scoreline on the other side.

Nozinan 100 mg tablets are: film-coated, round, cream-white colored, with Nozinan 100 imprinted on one side and with a scoreline on the other side.

Package sizes of 20 and 100 tablets are available for Nozinan 25 mg.

Package sizes of 20 and 100 tablets are available for Nozinan 100 mg.

Not all package sizes are marketed.

This leaflet does not contain all the information about your medicine. If you have any question or are not sure about anything, please ask your doctor.

Registered holder name and address: sanofi-aventis Israel Ltd., 10 Beni Gaon Street, Netanya.

Manufacturer name and address: Famar Lyon, France. This leaflet was checked and approved by the Ministry of Health in December 2013.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Nozinan 25 mg: 1079820997

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