

ANNEX IIIB

PACKAGE LEAFLET: INFORMATION FOR THE USER

Name of the medicine

Nozinan 100 mg scored film-coated tablets

Levomepromazine

Boxed text

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 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What **Nozinan** 100 mg scored film-coated tablets are and what they are used for
2. What you need to know before you take **Nozinan** 100 mg scored film-coated tablets
3. How to take **Nozinan** 100 mg scored film-coated tablets
4. Possible side effects
5. How to store **Nozinan** 100 mg scored film-coated tablets
6. Contents of the pack and other information.

1. WHAT Nozinan 100 mg scored film-coated tablets ARE AND WHAT THEY ARE USED FOR

Pharmacotherapeutic group - ATC code: ANTIPSYCHOTIC – N05AA02

This medicine belongs to a group of medicines known as antipsychotics. It acts on the brain. It is used to treat a disease characterized by symptoms such as hearing, seeing or feeling things which do not exist, and having unusual suspicions, mistaken beliefs, erratic speech and behavior and emotional and social withdrawal. People with this disease may also feel depressed, guilty, anxious or tense.

This medicine is for adults only.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE Nozinan 100 mg scored film-coated tablets

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Do not take Nozinan 100 mg scored film-coated tablets:

- if you are allergic to the active ingredient (levomepromazine) or any of the ingredients of this medicine. The list of ingredients can be found in section 6,
- if you have difficulty urinating,
- if you have or are at risk for glaucoma (a disease affecting the eye where pressure of the liquid inside the eye is increased, which may affect your vision),
- if you have previously experienced a major drop in the number of certain white blood cells (agranulocytosis),
- if you are taking any of the following medicines:
 - cabergoline, quinagolide (medicines used to treat abnormal discharge of milk from the breasts),
 - citalopram or escitalopram (medicines used to treat anxiety or depression),
 - hydroxyzine (a medicine used to treat minor anxiety symptoms, hives (urticaria) and certain kinds of insomnia, and used as a premedication before general anesthesia),
 - piperazine (a medicine used to treat malaria, a disease caused by a parasite),
 - domperidone (a medicine used to treat nausea or vomiting).
- if you are allergic to wheat since this medicine contains wheat starch.

IF YOU ARE UNSURE OF ANYTHING, IT IS ESSENTIAL THAT YOU ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

Warnings and precautions

- This medicine contains a type of sugar (lactose). You should not take this medicine if you have galactose intolerance, Lapp lactase deficiency or glucose or galactose malabsorption syndrome (rare hereditary diseases),
- You may take this medicine if you have celiac disease (difficulty absorbing gluten by the intestines). This medicine contains wheat starch (a source of gluten), but only trace amounts, and is therefore considered safe for people with this condition.

Talk to your doctor before taking **Nozinan** scored film-coated tablets:

- if you have heart disease,
- if you have risk factors: for example, if you smoke or if you have high blood pressure, too much sugar, cholesterol or fat in the blood, this medicine should be used with caution because it may increase the risk of stroke,
- if you have liver or kidney disease,
- if you have had seizures recently or in the past or if you have epilepsy,
- if your prostate (the gland which produces sperm) has increased in size,
- if you have constipation.

This medicine should be used with caution:

- in elderly patients with dementia,
- if you or a family member have a history of blood clots, since taking antipsychotic drugs has been associated with the formation of blood clots.

During treatment

- You should tell your doctor immediately:
 - if you feel muscle stiffness, consciousness disorders and fever. In this case, you should stop treatment immediately and inform your doctor,
 - if you have fever, are pale, have heavy sweating, or any other sign which suggests infection. This is because this medicine may occasionally cause a decrease in the number of white blood cells you have, which increases the risk of infection,
 - if you have constipation that lasts a long time, as well as bloating and stomach pain. This is because this medicine may, in very rare cases, cause a blockage in your bowels (intestinal obstruction) and/or very serious inflammation of the intestines, which may lead to destruction of local tissue (necrosis).
- In order to detect any potential heart disorders, your doctor may ask you to have an examination to measure the electrical activity of your heart (electrocardiogram). This is because some medicines from the same group as **Nozinan** (antipsychotics) may, in very rare cases, cause heart rhythm disorders (see section 4),
- If you are diabetic or have risk factors for diabetes, you should monitor your blood sugar levels very closely.

Children and adolescents

This medicine is for adults only.

Other medicines and Nozinan 100 mg scored film-coated tablets

Do not take **Nozinan** with the following medicines:

- cabergoline, quinagolide (medicines used to treat excessive or abnormal secretion of breast milk),
- medicines that can cause serious heartbeat problems such as:
 - citalopram or escitalopram (medicines used to treat anxiety or depression),
 - hydroxyzine (a medicine used to treat minor anxiety symptoms, hives (urticaria) and certain kinds of insomnia, and used as a premedication before a general anesthetic),
 - domperidone (a medicine used to treat nausea and vomiting),
 - piperazine (a medicine used to treat malaria).

You must avoid taking **Nozinan** if you are already taking:

- a medicine used to treat Parkinson's disease,
- a medicine that contains alcohol,

- sodium oxybate (a medicine used to treat narcolepsy),
- a medicine that can cause serious heart rhythm disorders:
 - neuroleptics (medicines used to treat certain psychiatric disorders, such as amisulpride, chlorpromazine, cyamemazine, droperidol, fluphenazine, haloperidol, pimozide, pipamperone, pipotiazine, sulphiride, sultopride, tiapride, flupenthixol and zuclopenthixol),
 - antiparasitics (medicines used to treat diseases caused by parasites, such as chloroquine, halofantrine, hydroxychloroquine, lumefantrine, pentamidine),
 - antibiotics (medicines used to treat infections, such as intravenous erythromycin or spiramycin, moxifloxacin),
 - mizolastine (a medicine used to treat allergies),
 - anticancer medicines (medicines used to treat cancer, such as toremifene, arsenic compounds or vandetanib),
 - intravenous dolasetron (a medicine used in adults to treat or prevent nausea and vomiting caused by certain treatments or surgery),
 - intravenous vincamine (a medicine used to treat certain minor neurological disorders associated with aging),
 - diphemanil (a medicine used to treat gastric secretion disorders and excessive sweating),
 - prucalopride (a medicine used to treat constipation),
 - mequitazine (a medicine used to treat allergic rhinitis or urticaria),
 - antiarrhythmics (medicines used to control fast or irregular heartbeat, such as amiodarone, dronedarone, disopyramide, hydroquinidine, quinidine and sotalol),
 - methadone (a medicine used to treat addiction).

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Nozinan 100 mg scored film-coated tablets with food, drink and alcohol

You should avoid drinking alcoholic beverages during treatment with **Nozinan**.

Pregnancy, breast-feeding and fertility

Nozinan 100 mg scored film-coated tablets are not recommended during pregnancy. Talk to your doctor before taking this medicine:

- if you are a woman of childbearing age and not using effective contraception, or
- if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby.

Pregnancy

Do not use this medicine during pregnancy unless you are advised to do so by your doctor advice.

The following symptoms may occur in newborn babies whose mothers used **Nozinan** in the last trimester (last three months) of their pregnancy: shaking, muscle stiffness and/or weakness, sleepiness, restlessness, breathing problems and difficulty feeding. If your baby develops any of these symptoms, you need to contact your doctor.

If you find out that you are pregnant, consult your doctor as only he/she can decide whether it is necessary to pursue treatment.

Breast-feeding

This medicine passes into breast milk.

Breast-feeding is not recommended while you are taking this medicine.

Ask your doctor or pharmacist for advice before taking any medicine.

Fertility

Use of this medicine can lead to excessive levels of prolactine (a hormone that triggers milk production) in the blood, which may be associated with a decrease in fertility.

Driving and using machines

This medicine may cause drowsiness. If you feel drowsy, you should ask your doctor for his/her opinion before driving.

Nozinan 100 mg scored film-coated tablets contain wheat starch (gluten) and lactose.

3. HOW TO TAKE Nozinan 100 mg scored film-coated tablets

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

This medicine is for adults only.

The dose can vary. Your doctor will adjust it to suit your needs.

Method and route of administration

This medicine is for oral use.

Swallow the tablets whole with a large glass of water.

The tablets are scored. This means you can break them into 2 equal parts.

If you take more Nozinan 100 mg scored film-coated tablets than you should:

Tell your doctor immediately or go to the emergency medical service of the nearest hospital, since this medicine can cause serious heart disorders.

If you forget to take Nozinan 100 mg scored film-coated tablets:

Not applicable.

If you stop taking Nozinan 100 mg scored film-coated tablets:

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

The following effects may occur:

- feeling of dizziness when suddenly standing up from a lying or seated position,
- dry mouth, difficulty urinating, constipation, even intestinal blockage (intestinal obstruction),
- visual disturbances, including accommodation disorders (ability of the eye to adjust to different distances),
- drowsiness, anxiety, mood disorders,
- shaking, stiffness and/or abnormal movements,
- impotence, frigidity,
- weight gain,
- absence of menstrual period, enlarged breasts, abnormal discharge of breast milk,
- changes in blood sugar levels,
- changes in body temperature,
- venous blood clots, particularly in the legs (symptoms include swelling, pain and redness in the legs). The clots may pass through the blood vessels to reach the lungs, causing chest pain and difficulty breathing. If you experience any of these symptoms, see a doctor immediately.

The following may occur rarely:

- heart rhythm disorders (possibly life-threatening in exceptional cases),
- abnormal results for certain laboratory tests (positive results for certain antinuclear antibodies),
- allergic skin reaction, excessive reaction of the skin to the sun or ultraviolet rays,
- elevated transaminases (liver enzymes), jaundice (yellowing of the skin and eyes), hepatitis (inflammation of the liver).

The following may occur more rarely:

- fever, heavy sweating, paleness, muscle stiffness and consciousness disorders. If these signs occur, you must immediately stop treatment and contact your doctor or the emergency medical service of the nearest hospital,
- very serious inflammation of the intestines, which can lead to destruction of local tissue (necrosis).
- major drop in the number of certain white blood cells, which may potentially cause serious infection (agranulocytosis),
- painful, prolonged erection,
- brownish deposits in the eye, which generally do not affect vision.

Frequency unknown:

- withdrawal syndrome in newborn babies whose mothers took **Nozinan** during the last trimester (the last 3 months) of pregnancy. The frequency of these events is not known. (see sections "Pregnancy" and "Breast-feeding"),
- confusion, seizures,
- hyponatremia (decrease in the amount of sodium in the blood).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system, i.e. *Agence Nationale de Sécurité du Médicament et des Produits de Santé* (ANSM) under "réseau des Centres Régionaux de Pharmacovigilance" (network of Regional Pharmacovigilance Centers) – Website : www.ansm.sante.fr

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

5. HOW TO STORE Nozinan 100 mg scored film-coated tablets

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the box. The expiry date refers to the last day of that month.

Do not store above 25 °C.

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 100 mg scored film-coated tablets contain

- The active substance is:

Levomepromazine maleate acid 135.0 mg
Equivalent to levomepromazine base 100.0 mg
For one scored film-coated tablet.

- The other ingredients are:

Lactose, wheat starch, hydrated silica, white dextrin, magnesium stearate, hypromellose, polyethylene glycol 20 000 (PEG 20 000), titanium oxide, yellow iron oxide.

What Nozinan 100 mg scored film-coated tablets look like and contents of the pack

This medicine is a scored film-coated tablet.

Box of 20 tablets.

Marketing Authorization Holder

Sanofi aventis France
82, avenue Raspail
94250 Gentilly, France

Operator

Sanofi aventis France
82, avenue Raspail
94250 Gentilly, France

Manufacturer

Sanofi SPA
SS 17 km 22
67019 Scoppito (AQ)
Italy

or

Aventis Pharma
Rainham Road South
Dagenham Essex RM10 7XS
United Kingdom

Names of the medicinal product in the Member States of the European Economic Area

Not applicable.

This leaflet was last revised in:

[to be filled in subsequently by the MA Holder]

Other

Detailed information on this medicine is available on the ANSM website (France).