

PACKAGE LEAFLET: INFORMATION FOR THE USER

NOZINAN

25 mg film-coated tablets / 100 mg film-coated tablets

LEVOMEPRMAZINE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

1. What NORVASC is and what it is used for
2. Before you take NORVASC
3. How to take NORVASC
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1. WHAT NORVASC IS AND WHAT IS IT USED FOR

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. BEFORE YOU TAKE NORVASC

If your doctor has told you that you are intolerant to certain sugars, consult him/her before taking this medicine.

Do not take Nozinan film-coated tablets:

- if you are allergic to the active ingredient (levomepromazine) or to any of the other ingredients of this medicine (listed 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 a medicine containing cabergoline, quinagolide (medicines used to treat abnormal secretion of breast milk) or containing citalopram or escitalopram (medicines used to treat anxiety or depression).
- 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.

Take special care with Nozinan film-coated tablets:

- This medicine contains a type of sugar (sucrose). You should not take it if you are galactose intolerant, if you have 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, but only traces, and is therefore considered safe for people with this condition.

Talk to your doctor before taking Nozinan 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 that you 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.

Taking or using other medicines

Do not take Nozinan with medicines containing cabergoline, quinagolide (medicines used to treat excessive or abnormal secretion of breast milk) or containing citalopram or escitalopram (medicines used to treat anxiety or depression).

You must avoid taking Nozinan if you are already taking:

- antibiotics (medicines used to treat infections, such as intravenous erythromycin or spiramycin, moxifloxacin, or levofloxacin),
- 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),
- domperidone (a medicine intended to relieve nausea and vomiting, feeling of distention, gastric discomfort or reflux),
- a medicine used to treat Parkinson's disease,
- a medicine that contains alcohol,
- a medicine that can cause serious heart rhythm disorders:
- medicines used to control fast or irregular heartbeat, such as amiodarone, dronedarone, disopyramide, dofetilide, hydroquinidine, ibutilide, quinidine, and sotalol (antiarrhythmics),
- medicines used to treat certain psychiatric disorders, such as amisulpride, chlorpromazine, cyamemazine, droperidol, fluphenazine, pericyazine, haloperidol, pimozide, pipamperone, sulphiride, sultopride, tiapride, flupenthixol, and zuclopenthixol (neuroleptics),
- medicines used to treat diseases caused by parasites, such as halofantrine, lumefantrine, pentamidine (antiparasitics),
- methadone (a medicine used to treat addiction).

Tell your doctor or pharmacist if you are using or have recently used any other medicines, including medicines obtained without a prescription.

Food and drink

You should avoid drinking alcoholic beverages during treatment with Nozinan.

Pregnancy

This medicine should only be used during pregnancy on your doctor's advice.

The following symptoms may occur in newborn babies whose mothers have used Nozinan in the last trimester (last three months) of their pregnancy: shaking, muscle stiffness and/or weakness, sleepiness, agitation, 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.

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

Breast-feeding

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

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

Driving and using machines

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

Important information about some of the ingredients of Nozinan film-coated tablets

This medicine contains sugar (lactose) and wheat starch (gluten) (See "Take special care with Nozinan film-coated tablets" and "Do not take Nozinan film-coated tablets").

3. HOW TO TAKE NORVASC

Dosage

This medicine is for adults only.

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

Always take the dose recommended by your doctor. If you are unsure of anything, ask your doctor or pharmacist.

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 that you can break them into 2 equal parts.

If you take more Nozinan 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.

4. POSSIBLE SIDE EFFECTS

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

The following effects can occur:

- feeling of dizziness when suddenly standing up from the 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, generally with no effect on vision.

Frequency unknown:

- withdrawal syndrome in newborn babies whose mothers have taken Nozinan during the last trimester (the last 3 months) of pregnancy (see Sections "Pregnancy" and "Breastfeeding"),

- confusion, seizures,
- hyponatremia (drop 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. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE NORVASC

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.

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.

5. FURTHER INFORMATION

What NOZINAN film-coated tablets contain

Nozinan 25 mg film-coated tablets

The active substance is:

Levomepromazine maleate, expressed as base 25 mg for one film-coated tablet.

Nozinan 100 mg film-coated tablets

The active substance is:

Levomepromazine maleate, expressed as base 100 mg for one film-coated tablet.

The other ingredients are:

Lactose, wheat starch, hydrated silica, white dextrin, magnesium stearate, hypromellose, macrogol 20 000.

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

Nozinan 25 mg film-coated tablets

This medicine is a film-coated tablet. Each box contains 20 film-coated tablets.

Nozinan 100 mg film-coated tablets

This medicine is a film-coated tablet. Each box contains 20 film-coated tablets.

Marketing Authorization Holder and Operating Company

Sanofi-aventis France, 1-13, boulevard Romain Rolland, 75014 Paris – France

Manufacturer

Famar Lyon, 69230 Saint Genis Laval – France or

Aventis Pharma, Dagenham – United Kingdom