

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.



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 amitriptylinoxide and drugs for other mental health disorders (i.e. antipsychotics)
- desferrioxamine (for iron poisoning)
- adrenaline (epinephrine) in patients overdosed with antipsychotic 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.

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, hypothermia (abnormally low body temperature) and severe extrapyramidal dyskinesias (involuntary movements).

Turn Over

DATE: 17-07-2019	CODE: 677198	REPLACED CODE: 89031270	VERSION: 5	BRAILLE: Justella num.
DESCRIPTION: IST NOZINAN 25MG GB 101	SAP/ID N°: 89031985	SAP/ID N°: 89031270	PROOF N°: 5	PACKAGING LINE: -
PACK. ITEM: Istruzioni	TECHNICAL DRAW. CODE: 62C0018 V.1.0	EXT. DIM.: 167x315mm	DIE CUT: -	MIN. FONT SIZE: 9,5 pt su 11 pt
MARKET: GB: GREAT BRITAIN	LAETUS: 1000111011	EXT. DIM.: singola	PRODUCT LOGO: -	PAGE: 1 / 2
COLORS: ■ Reflex Blue			IMPIANTO DI PROPRIETÀ: Sanofi S.p.A.	
Text approval Date: _____	Signature: _____			
Final approval Date: _____	Signature: _____			
Arkhé S.n.c. Tel. 0862.404140 Fax 0862.090006				
Verificare la corrispondenza dell'artwork approvato - la nostra responsabilità è limitata al rilascio delle file fornite.				

1 - Prima realizzazione 2 - Modifica testo reg. 3 - Ins. GMID 4 - Modifica testo reg. 5 - Modifica testo reg.

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 involuntary 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 water (urine) becomes darker
- you have discolouration 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

Sanofi,
410 Thames Valley Park Drive,
Reading, Berkshire,
RG6 1PT, UK
Tel: 0845 372 7101
Email: uk-medicalinformation@sanofi.com


Manufacturer

Sanofi S.p.A.
Strada Statale 17, Km 22,
67019 Scoppito (L'Aquila),
Italy

This leaflet was last revised in July 2019

© Sanofi, 2019

89031985 - 677198

DATE: 17-07-2019	CODE 677198	REPLACED CODE	VERSION:	BRILLE: fustella num.
DESCRIPTION: IST NOZINAN 25MG GB 101	SAP/ID N°: 89031985	SAP/ID N°: 89031270		
PACK. ITEM: Istruzioni	TECHNICAL DRAW. CODE: 62C0018 V.1.0		PROOF N°: 5	PACKAGING LINE:
MARKET: GB: GREAT BRITAIN	LAETUS: 1000111011	EXT. DIM.: 167x315mm	DIE CUT: -	MIN. FONT SIZE: 9,5 pt su 11 pt
COLORS: ■ Reflex Blue		PRODUCT LOGO:	PAGE: 2 / 2	
		IMPIANTO DI PROPRIETÀ:	Sanofi S.p.A.	
Text approval Date: _____	Signature: _____	 Arkhe S.n.c. Tel. 0862.404140 Fax 0862.090006		
Final approval Date: _____	Signature: _____			

1 - Prima realizzazione 2 - Modifica testo reg. 3 - Ins. GMID 4 - Modifica testo reg. 5 - Modifica testo reg.