

PACKAGE LEAFLET: Information for the patient

NICORDIN

Tablets – 20 mg

(Nitrendipine)

Read this leaflet carefully before you start taking this medicine.

- 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 symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, talk to your doctor or pharmacist.

In this leaflet:

1. What Nicordin is and what it is used for
2. Before you take Nicordin
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4. Possible side effects
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1. WHAT NICORDIN IS AND WHAT IT IS USED FOR

Nicordin is a medicinal product for the treatment of hypertension. The active substance nitrendipine is a calcium antagonist of the dihydropyridine type.

Nicordin is used for the treatment of essential hypertension (hypertension which is not correlated with the disease of a specific organ).

2. BEFORE YOU TAKE NICORDIN

Do not take Nicordin:

- if you are hypersensitive (allergic) to nitrendipine, dihydropyridine calcium antagonists of the 1,4-type or to any of the other excipients of Nicordin;
- if you have cardiovascular shock;

- if you have higher grade stenosis of the heart valve (aortic valve stenosis, sub-aortic valve stenosis);
- in acute myocardial infarction (within the first 4 weeks);
- in unstable angina pectoris;
- during pregnancy and lactation;
- simultaneously with rifampicin.

Take special care with Nicordin:

- if the weakening of the cardiac muscle (decompensated heart failure) is not adequately treated; a particularly careful medical supervision is required in this case;
- if you have severe liver disorders; in these cases the treatment will be started with the lowest dose and continued under close medical supervision;
- in angina pectoris; very rarely, especially at the start of treatment, angina pectoris may occur;
- in case of simultaneous administration of CYP3A4 system inhibitors or inducers; the blood pressure must be monitored.

Children

There is not sufficient experience of its use in children and adolescents under the age of 18 years.

Elderly

A rapid drop in blood pressure is not desirable in elderly patients with high blood pressure. The dosage in these patients should be associated with frequent monitoring of blood pressure. See also "How to take Nicordin".

This medicine contains less than 1 mmol sodium (23 mg) per one tablet, that is to say essentially "sodium free".

Taking Nicordin with other medicines

Tell your doctor or pharmacist if you are taking or have recently taken other medicines, including medicines taken without a prescription.

Nicordin is affected as follows:

Increase of the effect and possibly of the side effects

- The antihypertensive effect of Nicordin can be enhanced by other antihypertensive drugs.
- Concomitant use of Nicordin and beta-blockers requires regular monitoring of patients because it can lead to increased blood pressure lowering; occasionally, heart failure may also develop. The concomitant administration of intravenous beta-blockers and Nicordin should be avoided.
- Cimetidine may lead to an increase in the nitrendipine plasma levels and thus to increased nitrendipine effect.
- Inhibitors of the CYP3A4 system can increase nitrendipine plasma concentrations. Such medicines are:
 - some macrolide class antibiotics, e.g. **erythromycin**,
 - drugs for the treatment of AIDS, e.g. **ritonavir**,
 - some antifungals e.g. **ketoconazole**,
 - **nefazodone**, **fluoxetine**, which are used to treat depression,
 - **quinupristin / dalfopristin** a combination of two antibiotics,
 - **valproic acid**, anti-seizure medication.

Reduction of the effect

- After gaining experience with the calcium antagonist nifedipine, it is expected that due to its enzyme-inducing effect, rifampicin accelerates the metabolism of nitrendipine. This could make the potency of nitrendipine weaker. Therefore, when co-administered with rifampicin, a dose adjustment of nitrendipine is needed and if necessary, supplement therapy.
- Antiepileptic drugs which are inducers of CYP3A4 system, like: phenytoin, phenobarbital, carbamazepine, can decrease nitrendipine blood levels, thus reducing its action.

Nicordin influences the effect of the following medicines

- Concomitant administration of digoxin may lead to increased digoxin plasma levels. Therefore, care is required for symptoms of digoxin overdose and if necessary, the digoxin plasma levels can be determined. If necessary, a reduction of the digoxin dose should be done.
- Calcium antagonists can increase the negative inotropic effect of antiarrhythmic agents (e.g. amiodarone, quinidine) and lead to sinus arrest and atrioventricular block.

- The effect of certain muscle relaxants (pancuronium, vecuronium halide) can be extended.
- Concomitant administration of prazosin can cause severe hypotension.

Taking Nicordin with food and drinks

Grapefruit juice inhibits the oxidative degradation of nitrendipine. The resulting higher plasma concentrations may lead to increased blood pressure lowering.

Pregnancy and lactation

Talk to your doctor or pharmacist before taking / using any medicine.

Pregnancy

During pregnancy, Nicordin should not be used, since experimental studies in animals with high doses have shown evidence of damage to the offspring. Human experiences are not available.

Lactation

Nitrendipine, the active substance of Nicordin passes in small amounts into breast milk. Since there is no experience of possible effects on the infant, lactation should be discontinued if treatment with Nicordin is necessary during this period.

Effects on ability to drive and use machines

Treatment with this drug requires regular medical controls.

Given that the occurring reactions are individually different, the ability to react may be changed and that will affect the ability to drive, operate machinery or engage in potentially hazardous activities. This happens even more at the start of treatment, when dose increases and the drug is changed, as well as in combination with alcohol.

3. HOW TO TAKE NICORDIN

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

Unless otherwise prescribed by the doctor, the usual dose is:

The treatment should be carried out individually depending on the severity of the disease.

Unless otherwise prescribed, the following doses should be used:

Once daily (in the morning) 1 tablet Nicordin (20 mg of nitrendipine).

The daily dose can be gradually increased in case of insufficient blood pressure reduction up to 1 tablet Nicordin twice daily (40 mg of nitrendipine).

The maximum daily dose is 40 mg of nitrendipine.

In patients with chronic liver disease, especially in old patients, the elimination of the drug may be delayed, which may lead to unwanted reduction of blood pressure. The dosage in these patients should then be ½ tablet Nicordin (10 mg of nitrendipine) with frequent blood pressure monitoring. However, should the blood pressure increase too much, a change of the drug may be necessary.

Method and duration of treatment

Take the tablets without chewing them, after the meals, and with sufficient fluid (a glass of water [200 ml]).

They should not be combined with grapefruit juice, as this can lead to a greater effect of Nicordin (see "Taking Nicordin with food and drinks").

The duration of use is decided by the doctor.

Talk to your doctor or pharmacist if you have the impression that the effect of Nicordin is too strong or too weak.

If you take more Nicordin than you should

Contact immediately your doctor if you think you have taken an overdose, so he will decide for further actions!

An acute overdose is associated with severe skin rash (flushing), headache, severe hypotension, tachycardia or bradycardia, and altered mental status till deep unconsciousness.

If you forget to take Nicordin

Do not take a double dose to make up for a forgotten dose. Continue the treatment with the recommended dose.

If you stop taking Nicordin

An interruption or change of the dosage may be made only on medical advice.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, nitrendipine can cause side effects, although not every patient gets them.

For the evaluation of side effects, the following indicators are used:

Very common	more than 1 patient in 10
Common	1 to 10 patients in 100
Uncommon	1 to 10 patients in 1,000
Rare	1 to 10 patients in 10,000
Very rare	less than 1 patient in 10,000
Unknown	Frequency cannot be estimated from the available data

Possible side effects

Very common: (particularly at the beginning of treatment, transient).

- headache;
- peripheral oedema;
- flushing.

Common:

- particularly at the beginning of treatment, angina pectoris attacks may occur, or in patients with pre-existing angina pectoris there may be an increase in the frequency, duration and severity of the attacks; palpitation; tachycardia.

Uncommon:

- paraesthesia, dizziness, tiredness, syncope, restlessness;
- abnormal vision, blurred vision;
- vertigo;
- hypotension;
- dyspnoea;
- nausea, vomiting, abdominal pain, diarrhoea, constipation;
- skin and hypersensitivity reactions such as pruritus, urticaria, exanthema, photosensitisation;
- myalgia, arthralgia;
- more frequent urination, polyuria;
- weight gain, sweating.

Rare:

- leucocytoclastic vasculitis;
- hepatic function disorders (elevated transaminase levels).

Very rare:

- leucopenia, agranulocytosis;
- myocardial infarction;
- gingival hyperplasia;
- exfoliative dermatitis, angioedema;
- erection disorders, gynaecomastia, menorrhagia;
- fever.

Talk to your doctor or pharmacist if any of the side effects gets serious or if you notice any side effects not listed in this leaflet.

5. HOW TO STORE NICORDIN

Keep out of the reach and sight of children!

Do not store above 25°C!

Store in the original packaging to protect it from light!

Pull the tablet out of the blister just before use.

You should not use this medicine after the expiry date stated on the box and blister.

6. OTHER INFORMATION

What Nicordin contains

The active substance is nitrendipine.

Each tablet contains 20 mg of nitrendipine.

The excipients are: maize starch, microcrystalline cellulose, crospovidone, sodium lauryl sulphate, magnesium stearate.

Content of the packaging

Box with 30 tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania.

Tel.: +355 4 23 89 602

This leaflet was last revised in September 2023.