

Package leaflet: Information for the user

Nicorandil 10mg Tablets

Nicorandil 20mg Tablets

Nicorandil

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 Nicorandil Tablets are and what they are used for
2. What you need to know before you take Nicorandil Tablets
3. How to take Nicorandil Tablets
4. Possible side effects
5. How to store Nicorandil Tablets
6. Contents of the pack and other information

1. WHAT NICORANDIL TABLETS ARE AND WHAT THEY ARE USED FOR

The name of your medicine is Nicorandil 10mg Tablets or Nicorandil 20mg Tablets (referred to as Nicorandil Tablets throughout this leaflet). The active ingredient in this medicine is called nicorandil. This belongs to a group of medicines called 'potassium-channel activators'.

It works by increasing the blood flow through the blood vessels of the heart. It improves the blood and oxygen supply of your heart muscle and reduces its workload.

Nicorandil Tablets are used to prevent or attenuate painful, straining symptoms (angina pectoris) of your heart disease. It is used in adult patients who do not tolerate or cannot take heart medicines called beta-blockers and/or calcium antagonists.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE NICORANDIL TABLETS**Do not take Nicorandil Tablets if:**

- You are allergic (hypersensitive) to nicorandil or any of the other ingredients of this medicine (listed in section 6).
Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- You have low blood pressure (hypotension). Signs include feeling dizzy, light-headed or faint.
- You have heart problems such as cardiogenic shock, or left ventricular failure with low filling pressure or cardiac decompensation or shock.
- You are taking medicines to treat erectile dysfunction (impotence) such as sildenafil, tadalafil, vardenafil (phosphodiesterase inhibitors) or medicines to treat pulmonary hypertension such as riociguat (guanylate cyclase stimulators). This may seriously affect your blood pressure.
- You have low blood volume.
- You have a build-up of fluid in the lungs (pulmonary oedema).

Do not take this medicine if any of these apply to you. If you are not sure, talk to your doctor or pharmacist before taking Nicorandil Tablets.

Warnings and precautions

Talk to your doctor or pharmacist before taking Nicorandil Tablets.

Stop taking straight away nicorandil and talk to your doctor if you experience any of the following:

- Nicorandil may cause injuries to your gastrointestinal tract such as ulcers. This can develop problems such as bleeding, fistula, holes, abscess, especially if you have diverticular disease (a digestive condition affecting the large intestine).
- If your eyes become red, itchy or swollen. You may have eye injuries, stop taking Nicorandil Tablets and contact your doctor immediately.
- If you have skin ulcers.
- If you have mouth ulcers.

These side effects can occur at the beginning of treatment or later in the treatment course. The only possible treatment is to stop nicorandil. Do not take aspirin or any medicines for inflammation (corticosteroids).

Talk to your doctor or pharmacist before taking Nicorandil Tablets:

- If you have a low blood pressure.
- If you have low blood potassium level and your doctor has prescribed potassium supplements, or if you are suffering from renal impairment or taking other medicinal products that may increase potassium levels.
- If you have heart problems such as heart failure.
- If you have glucose-6-phosphate dehydrogenase deficiency.

Children

Nicorandil Tablets are not recommended in children.

Other medicines and Nicorandil Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because Nicorandil Tablets can affect the way some other medicines work. Also some medicines may affect the way Nicorandil Tablets work.

Do not take Nicorandil Tablets, and talk to your doctor if you are taking the following:

- Medicines for erectile dysfunction (impotence) such as sildenafil, tadalafil or vardenafil
- Medicines to treat pulmonary hypertension such as riociguat.

Tell your doctor if you are taking any of the following:

- Medicines that widen the blood vessels (vasodilators)
- Medicines to treat high blood pressure
- Medicines for depression
- Medicines for inflammation (corticosteroids such as prednisolone, non-steroidal anti-inflammatory drugs such as ibuprofen)
- Medicines that increase blood potassium levels
- Dapoxetine, a medicine used to treat premature ejaculation
- Aspirin (acetylsalicylic acid)

Nicorandil Tablets with alcohol

Nicorandil may lower your blood pressure. If you drink alcohol while you are treated with Nicorandil Tablets your blood pressure may be decreased even further.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You should avoid taking this medicine while you are pregnant.

It is not known whether nicorandil passes into human milk. You should not breast-feed while you are taking Nicorandil Tablets.

Driving and using machines

Nicorandil Tablets may cause dizziness or weakness. If this happens, do not drive or use any tools or machines.

3. HOW TO TAKE NICORANDIL TABLETS

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

Taking this medicine

- Take this medicine by mouth
- Swallow the tablets with a glass of water. Do not crush or chew the tablets. Nicorandil Tablets can be divided into equal halves.
- Do not take out or separate tablet from the blister strip until intake.
- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor.

The recommended dose is:

- The usual starting dose is 10mg twice daily.
- In case you are particularly prone to headache, a lower dose of 5mg (half of a 10mg tablet) twice daily might be prescribed by your doctor, for the first few days (2 to 7 days).
- Your doctor may increase the dose up to 20mg twice daily depending on your needs, response to treatment and tolerance.

Preferably take one dose in the morning and one in the evening.

If you take more Nicorandil Tablets than you should

If you take more tablets than you should or a child has swallowed any of your tablets, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken. You may feel blood pressure lowering effect such as dizziness, feeling of weakness. You may also feel your heart is beating irregularly and faster.

If you forget to take Nicorandil Tablets

If you forget a dose, take it as soon as you remember, unless it is nearly time for your next dose. Do not take a double dose to make up for a forgotten dose.

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.

Talk straight away to your doctor if you experience any of the following:

- Very fast, uneven or forceful heart-beat (palpitations) (Common side effect – may affect up to 1 in 10 people)
- Yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine – This may be signs of liver problems. (Very rare side effect – may affect up to 1 in 10,000 people)
- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (Very rare side effect – may affect up to 1 in 10,000 people)

Nicorandil may cause injuries to your gastrointestinal tract such as ulcers in the mouth, tongue,

stomach, guts (small and large), back passage. This can develop problems such as bleeding (blood in your stools or vomit), fistula (abnormal tube-like passage from one body cavity to another or to the skin), holes, abscess, weight loss. Ulcers can occur at other site such as: skin, genital tract and nasal passages or around a stoma (in those with an artificial opening for waste removal such as a colostomy or ileostomy).

Other possible side effects include:

Very common (may affect more than 1 in 10 people)

- Headache – This especially occurs during the first few days of treatment. Your doctor may progressively increase the dose to reduce the frequency of headaches.

Common (may affect up to 1 in 10 people)

- Dizziness
- Flushing of the skin
- Feeling sick (nausea)
- Being sick (vomiting)
- Feeling of weakness.

Uncommon (may affect up to 1 in 100 people)

- Decrease in blood pressure.

Rare (may affect up to 1 in 1,000 people)

- Rash
- Itching
- Aching muscles not caused by exercise (myalgia).

Very rare (may affect up to 1 in 10,000 people)

- High potassium levels in the blood (hyperkalaemia)
- Red, itchy, swollen or watery eyes (conjunctivitis)
- Eye injuries
- Cornea injuries
- Stomach aches.

Not known (frequency cannot be estimated from the available data)

- Double vision (diplopia).

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 (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

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5. HOW TO STORE NICORANDIL 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 blister or carton after EXP. The expiry date refers to the last day of that month.

Store below 25°C. Store in the original package to protect from moisture.

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 to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Nicorandil Tablets contain

- The active substance is nicorandil. Each 10mg tablet contains 10mg nicorandil. Each 20mg tablet contains 20mg nicorandil.
- The other ingredients are: cetyl alcohol, mannitol, croscarmellose sodium, povidone and sodium stearyl fumarate.

What Nicorandil Tablets look like and contents of the pack

The tablets are white to off-white, round, scored on one side and engraved with "10" or "20" on the other side.

The tablets can be divided into equal halves.

Nicorandil Tablets are available in packs of 10, 28, 30, 56 and 60 tablets in blister strips. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer: Dexcel® - Pharma Ltd., 7 Sopwith Way, Drayton Fields, Daventry, Northamptonshire, NN11 8PB, UK

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