

Package leaflet: Information for the user

Nicorandil 10 mg Tablets
Nicorandil 20 mg 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 10 mg Tablets or Nicorandil 20 mg Tablets (referred to as Nicorandil Tablets throughout this leaflet). Nicorandil Tablets contain the active substance "nicorandil". This belongs to a group of medicines called 'potassium-channel activators'.

Nicorandil Tablets are used to prevent or reduce painful signs ("angina pectoris") of your heart disease. It is used in adults who cannot take heart medicines called "beta-blockers" or "calcium antagonists".

Nicorandil Tablets work by increasing the blood flow through the blood vessels of the heart. They improve the blood and oxygen supply of your heart muscle and reduces its workload.

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 severe 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.
- 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)]. Your blood pressure may be affected if these medicines are taken with Nicorandil Tablets.
- You have low blood volume.
- You have a build-up of fluid in the lungs ("pulmonary oedema").

Do not take Nicorandil Tablets if any of the above 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 straight away if you notice any of the following serious side effects during treatment:

- red, itchy, swollen or watery eyes.
- ulcers in your mouth, stomach, guts (small and large) or back passage. These may cause blood in your stools or vomit, a fistula (abnormal tube-like passage from one body cavity to another or to the skin), a hole, abscess or weight loss. Ulcers may also develop on the skin, genital tract and nasal passages or around a stoma (where there is an artificial opening for waste removal such as a colostomy or ileostomy). These are more likely to happen if you have a problem with your large intestine ('diverticular disease').

Talk to your doctor before taking medicines for inflammation (corticosteroids) or non-steroidal anti-inflammatory medicines including aspirin, with Nicorandil Tablets. If taken together, you may be more likely to get ulcers or the other problems mentioned above.

These side effects can happen at the beginning of treatment or later in treatment. Talk to your doctor straight away if you notice any of the signs above. See section 4 for a full list of side effects.

Talk to your doctor or pharmacist before taking Nicorandil Tablets if:

- you have low blood pressure.
- you have low blood potassium levels and are taking potassium supplements.
- You have kidney problems or are taking other medicines that may increase potassium levels
- you have heart problems such as heart failure.
- you have a genetic condition called "glucose-6-phosphate dehydrogenase deficiency".

If any of the above apply (or you are not sure), talk to your doctor or pharmacist before taking Nicorandil Tablets.

Children

Nicorandil Tablets are not recommended for use 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 this medicine, and talk to your doctor if you are taking any of the following:

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

Do not take this medicine and talk to your doctor or pharmacist if any of the above apply to you.

Tell your doctor before taking Nicorandil Tablets, if you are taking any of the following:

- Medicines to treat high blood pressure
- Medicines that widen the blood vessels (vasodilators)
- Medicines that increase blood potassium levels
- Dapoxetine – a medicine used to treat premature ejaculation
- Medicines for inflammation – corticosteroids and non-steroidal anti-inflammatory drugs such as ibuprofen. If taken with Nicorandil Tablets you may be more likely to get ulcers
- Medicines for depression
- Aspirin (acetylsalicylic acid)

Nicorandil Tablets with alcohol

Nicorandil may lower your blood pressure. If you drink alcohol while you are being treated with Nicorandil Tablets your blood pressure may become even lower.

Pregnancy and breast-feeding

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 if you are pregnant.

It is not known whether nicorandil passes into your breast-milk. You should not breast-feed while you are taking this medicine.

Driving and using machines

Nicorandil Tablets may make you feel dizzy or weak. If this happens, do not drive or use any tools or machines.

Nicorandil Tablets contain less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

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.

How much to take

The recommended dose is:

- 10 mg, twice a day
- In case you get headaches, your doctor may give you a lower dose of 5 mg, twice a day for the first 2 to 7 days.
- Your doctor may increase your dose up to 20 mg, twice a day. This will depend on your needs, response and tolerance to treatment.

Taking this medicine

- Take one dose in the morning and one in the evening.
- 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 doses.
- Do not take the tablet out of the blister strip until you are about to take it.
- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor.

If you take more Nicorandil Tablets than you should

If you take more Nicorandil Tablets than you should or a child swallows any of the tablets, talk to a doctor or go to hospital straight away. Take the medicine pack with you. This is so the doctor knows what you have taken. You may feel dizzy or weak – signs of low blood pressure. You may also feel your heart beating irregularly and faster.

If you forget to take Nicorandil Tablets

If you forget a dose, take it as soon as you remember. However, if it is nearly time for your next dose, skip the missed 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.

Serious side effects

Talk to your doctor straight away if you notice any of the following serious side effects:

- Red, itchy, swollen or watery eyes, including problems (inflammation or ulcer) with parts of the eye called the 'cornea' and 'conjunctiva' (uncommon, may affect up to 1 in 100 people).
- Ulcers in your mouth, stomach, guts (small and large) or back passage (common, may affect up to 1 in 10 people). These may cause blood in your stools or vomit, a fistula (abnormal tube-like passage from one body cavity to another or to the skin – uncommon, may affect up to 1 in 100 people), a hole, abscess or weight loss. Ulcers may also develop on the skin, genital tract and nasal passages or around a stoma (where there is an artificial opening for waste removal such as a colostomy or ileostomy). These are more likely to happen if you have a problem with your large intestine (diverticular disease).

These side effects can happen at the beginning of treatment or later in treatment.

Talk to your doctor straight away if you notice any of the serious side effects above.

Other side effects:

Tell your doctor or pharmacist if you notice any of the following side effects:

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

- Headache – especially during the first few days of treatment. Your doctor may start you on a low dose and increase it slowly to reduce the frequency of headaches.

Common (may affect up to 1 in 10 people)

- Feeling dizzy
- Flushing of the skin
- Feeling sick (nausea)
- Being sick (vomiting)
- Feeling weak
- Very fast, uneven or forceful heart-beat (palpitations)
- Skin abscess (swollen, pus-filled lump that appears within or below the skin's surface)
- Ulcers (mouth, small and large intestines, anal)

Uncommon (may affect up to 1 in 100 people)

- Low blood pressure
- Abscess (genital, anal or other gastrointestinal locations)
- Corneal ulcer, conjunctival ulcer, conjunctivitis

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

- Rash
- Itching
- Aching muscles not caused by exercise

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

- Abdominal pain (including stomach ache)
- High potassium levels in the blood (hyperkalaemia)
- Yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine – these may be signs of liver problems
- Swelling of the face, lips, mouth, tongue or throat which may cause problems swallowing or breathing

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

- Double vision
- Weakness or paralysis of eye muscles affecting the movement of the eye, often associated with headache

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 HPRA Pharmacovigilance, website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

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 in order 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 protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Nicorandil Tablets contain

- The active substance is nicorandil. Each 10 mg tablet contains 10 mg nicorandil. Each 20 mg tablet contains 20 mg nicorandil.
- The other ingredients are: cetyl alcohol, mannitol (E 421), 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 doses.

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 GmbH, Carl-Zeiss-Straße 2, 63755 Alzenau, Germany

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