

Nicorandil 10 mg and 20 mg Tablets

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 in this leaflet

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1. What Nicorandil is and what it is used for

The name of your medicine is Nicorandil 10 mg or 20 mg Tablets (called Nicorandil in this leaflet). The active ingredient in this medicine is called Nicorandil. This belongs to a group of medicines called ‘potassium channel activators’.

Nicorandil is 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 and/or calcium antagonists. This medicine works by increasing the blood flow through the blood vessels of the heart. It improves the blood and oxygen supply to your heart muscle and reduces its workload.

2. What you need to know before you take Nicorandil

Do not take Nicorandil if you:

- are allergic to nicorandil or any of the other ingredients of this medicine (listed in section 6).
- have low blood pressure (hypotension).
- have heart problems such as cardiogenic shock, or left ventricular failure with low filling pressure or heart decompensation or shock.
- are taking medicines to treat erectile dysfunction 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.
- have low blood volume.
- have a build-up of fluid in the lungs (pulmonary oedema).

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

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, gut (small and large intestines) 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 this medicine. If taken together, you may be more likely to get ulcers or the other problems mentioned above.

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

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 if you:

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

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

Children

Nicorandil is not recommended for use in children.

Other medicines and Nicorandil

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Nicorandil can affect the way some other medicines work. Also some medicines may affect the way Nicorandil works.

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

- medicines for 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 if you are taking any of the following:

- medicines to treat high blood pressure.
- medicines that widen the blood vessels.
- medicines that increase blood potassium levels.
- dapoxetine, a medicine used to treat premature ejaculation.
- medicines for inflammation (corticosteroids, non-steroidal anti-inflammatory drugs such as ibuprofen). If taken with this medicine you may be more likely to get ulcers.
- medicines for depression.
- aspirin (acetylsalicylic acid).

Tell your doctor before taking this medicine, if you are taking any of the medicines above.

Nicorandil with alcohol

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

Pregnancy, 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 whilst you are pregnant.

It is not known whether Nicorandil passes into breast-milk. You should not breast-feed whilst taking this medicine.

Driving and using machines

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

Important information about some of the ingredients of nicorandil

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

3. How to take Nicorandil

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

The recommended dose is:

- The usual starting dose is 10 mg twice daily.
- If you get headaches, your doctor may give you a lower dose of 5mg, twice a day for the first 2 to 7 days.
- Your doctor may increase the dose up to 20 mg twice daily depending on your needs, response to treatment and tolerance.

Taking this medicine

- Preferably take one dose in the morning and one in the evening.
- Swallow the tablet (oral use).
- Do not take out or separate tablet from the blister strip until you are ready to take it.
- The tablet can be divided into equal doses.

Do not swallow the drying agent which is the bigger tablet on one end of each blister strip. It is included in the pack to protect Nicorandil tablets from moisture. On the blister, it is clearly indicated which tablet is the drying agent. If you do accidentally take any of these drying agent tablets, they should not harm you but you should talk to your doctor straight away.

If you take more Nicorandil than you should

If you take more tablets than you should, or if a child has swallowed any Nicorandil tablets, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. You may feel blood pressure lowering effects such as dizziness and/or feelings of weakness. You may also feel your heart is beating irregularly and faster.

If you forget to take Nicorandil

If you forget a dose, take it as soon as you remember it, unless it is nearly time for the next dose.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Nicorandil

If you have any further questions on the use of this product, 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 with a part of the eye called the 'cornea' (very rare, may affect up to 1 in 10,000 people).
- ulcers in your mouth, stomach, gut (small and large intestines) or back passage (rare, may affect up to 1 in 1,000 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), 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 – this usually occurs 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):

- dizziness
- very fast, uneven or forceful heart-beat (palpitations)
- flushing of the skin
- feeling sick (nausea)
- being sick (vomiting)
- feeling of weakness

Uncommon (may affect up to 1 in 100 people):

- low 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)
- 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 difficulty in swallowing or breathing
- 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 or pharmacist. 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 Nicorandil

Keep this medicine out of the sight and reach of children.

Do not use Nicorandil after the expiry date which is stated on the carton after 'EXP'. The expiry date refers to the last day of that month.

Do not use this medicine if you notice any visible signs of deterioration.

Store below 25°C. Keep the blister strip in the outer carton.

Use each blister strip within 30 days of opening.

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 tablet contains 10 mg or 20 mg of nicorandil.
- The other ingredients are maize starch, croscarmellose sodium, stearic acid and mannitol.

What Nicorandil tablets look like and contents of the pack

Nicorandil 10 mg tablets are white to off white coloured, round, flat bevelled edge, uncoated tablet debossed with 'ND 10' on one side and break line on other side. The tablet can be divided into equal halves.

Nicorandil 20 mg tablets are white to off white coloured, round, flat bevelled edge, uncoated tablet debossed with 'ND 20' on one side and break line on other side. The tablets can be divided into equal halves.

Nicorandil 10 mg & 20 mg tablets are presented in Alu-Alu fish bone blister strip of 10 tablets, in which each tablet is linked to a silica gel desiccant disc.

The blister strips are packaged in cartons of 10, 20, 30, 40, 50, 60, 70, 80, 90 or 100 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

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