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

1. WHAT NICORANDIL IS AND WHAT IT IS USED FOR

Nicorandil contains a medicine 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 is 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

Do not take Nicorandil:

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Nicorandil:

Stop taking nicorandil straight away and talk to your doctor if you experience 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. 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:

- 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 a genetic condition called "glucose 6 Phosphate Deshydrogenase deficiency".

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

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 may 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.

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-inflammatory steroidal drugs such as ibuprofen). If taken with Nicorandil you may be more likely to get ulcers
- Medicines for depression.
- Aspirin (acetylsalicylic acid).

Tell your doctor before taking Nicorandil if you are taking any of the medicines above

Nicorandil with alcohol

Nicorandil may lower your blood pressure. If you drink alcohol while you are treated with Nicorandil, 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 in human milk. You should not breast-feed while you are taking this medicine.

Driving and using machines

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

3. HOW TO TAKE NICORANDIL

Do not 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.
- In case you are particularly prone to headache, a lower dose of 5 mg 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 20 mg twice daily depending on your needs, response to treatment and tolerance.

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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 intake.

The 10 mg tablet can be divided into equal doses. For the 20 mg tablet, the score line is only there to help you break the tablet if you have difficulty swallowing it whole.

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 of your 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 effect such as dizziness, feeling of weakness. You may also feel your heart is beating irregularly and faster.

If you forget to take Nicorandil:

If you forget to take 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 to your doctor straight away if you notice any of the following:

- red, itchy, swollen or watery eyes, including problems (inflammation or ulcer) with a part of the eye called the 'cornea' (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)

Uncommon: may affect up to 1 in 100 people

- low blood pressure.
- abscess (genital, anal or other gastrointestinal locations)

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
- 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: it is not known how often these happen

- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard. 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 this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package in order to protect from moisture.

Do not swallow the drying agent which is contained in the strip.

Use the 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. CONTENT OF THE PACK AND OTHER INFORMATION

What Nicorandil contains:

- The active substance is nicorandil. Two strengths of tablets are available. The strengths are 10 mg and 20 mg.
- Other ingredients are maize starch, croscarmellose sodium, stearic acid and mannitol (E421).

What Nicorandil looks like and contents of the pack:

Nicorandil 10 mg tablets are white, round, scored on one side and embossed with '10' on the other side. Nicorandil 20 mg tablets are white, round, scored on one side and embossed with '20' on the other side. Nicorandil 10 mg tablets and 20 mg tablets are available in blister packs. Each blister contains 10 tablets. The blisters are packed in cartons of 60 tablets.

Marketing Authorisation Holder:

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Manufacturer:

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This leaflet was last revised in June 2024