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PACKAGE LEAFLET: INFORMATION FOR THE USER

Nicorandil 10 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 symptoms 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.

In this leaflet:

1. What Nicorandil is and what it is used for
2. Before you take Nicorandil
3. How to take Nicorandil
4. Possible side effects
5. How to store Nicorandil
6. Further information

1. WHAT NICORANDIL IS AND WHAT IT IS USED FOR

Nicorandil tablet 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 tablet 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.

You must talk to a doctor if you do not feel better or if you feel worse.

2. 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 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, wholes, 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 and contact your doctor immediately.

These side effects can occur at the beginning of treatment or latter 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.
- if you have ulcers in the stomach or gut
- if you have skin ulcers
- if you have mouth ulcers
- if you have been told by your doctor that you have a low blood volume or low systolic blood pressure
- if you have an acute build up of fluid in the lungs (acute pulmonary oedema)
- if you have recently had a heart attack (acute myocardial infarction)
- if you have glucose 6 Phosphate deshydrogenase deficiency.

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 medical products that may increase potassium levels.

Elderly patients
Elderly patients should take the lowest possible dose that relieves the complaints.

Children
Nicorandil is not recommended in children

Inform your doctor before treatment if any of the above mentioned conditions apply to you.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Nicorandil can affect the way some other medicines work and some medicines can affect the way nicorandil works. You must not take Nicornadil, and tell your doctor, if you are taking medicines for impotence such as sildenafil, tadalafil or vardenafil (phosphodiesterase 5 inhibitors).
Medicines to treat pulmonary hypertension such as riociguat.

These medicines are also used for a rare progressive disease of the blood vessels in the lung (pulmonary arterial hypertension). The simultaneous use of these medicines and Nicornadil can lead to a serious drop in blood pressure.

Tell your doctor if you are taking any of the following:
- medicines that widen the blood vessels (vasodilators)
- medicines used to treat high blood pressure
- medicines used to treat depression (tricyclic antidepressants)
- medicines that increase blood potassium levels.
- dapoxetine, a medicine used to treat premature ejaculation.
- aspirin (acetylsalicylic acid).

If you take one of these medicines together with Nicornadil your blood pressure could get too low.
If you take Nicornadil together with corticosteroids (medicines used to treat inflammation), perforations in the stomach or gut can occur.

Taking Nicorandil with food, drink and 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. Discuss with your doctor if it is appropriate for you to have alcohol while taking this medicine but be aware that the combination may adversely affect your ability to drive and use machinery (see *Driving and using machines below*).

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-fed while you are taking this medicine.

Driving and using machines
You may feel dizzy and or light-headed while taking this medicine. This may be more likely if you are taking other medicines (especially those used to treat high blood pressure and some medicines for depression) and if you have been drinking alcohol. If you are affected you should not drive, use machinery or take part in any activities where these effects may put you or others at risk.

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3. HOW TO TAKE NICORANDIL

Always take Nicorandil exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Method of administration
Take this medicine by mouth. Swallow the tablets whole with a sufficient amount of water (e.g. one glass of water). You can take the tablets with or without food. Do not crush or chew the tablets.

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.

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

Use in children
Nicorandil is not recommended for use in children

Elderly patients
Elderly patients should take the lowest possible dose that relieves the complaints.

Your doctor will decide how many tablets of Nicorandil you will have to take per day.

If you feel the effect of your medicine is too weak or too strong, **do not change the dose yourself,** but talk to your doctor.

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. This is so the doctor knows what you have or the child has taken. The following effects may happen: your blood pressure drops off and you may feel dizzy or weak, your heart may beat faster than normal or you have difficulty in breathing or wheezing.

If you forget to take Nicorandil
If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Nicorandil
Keep taking Nicorandil until your doctor tells you to stop. Do not stop taking Nicorandil because you feel better. If you stop, your illness may get worse or come back.

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.

Talk straight away to your doctor if you experience any of the following:
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), wholes, 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 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
- 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)
- 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
- Yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine – This 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.
By reporting side effects you can help provide more information on the safety of this medicine

5. HOW TO STORE NICORANDIL

Keep out of the sight and reach of children.

Do not use Nicorandil after the expiry date which is stated on the outer carton and the blister foil.

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.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Nicorandil contains
- The active substance is nicorandil. Each tablet contains 10 mg nicorandil.
- The other ingredients are sodium starch glycolate (type A), stearic acid, mannitol.

What Nicorandil looks like and contents of the pack
Nicorandil tablets are white to off-white round, flat tablets with a break line on one side.

They are supplied in blisters of 20, 30 or 60 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Strandhaven Limited T/A Somex Pharma
Ilford, Essex IG3 8BS, UK

Manufacturer
Bluepharma Indústria Farmacêutica, S.A
Cimo de Fala – S. Martinho do Bispo,
3045-016 Coimbra Portugal

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