

## PACKAGE LEAFLET: INFORMATION FOR THE USER

**Nicoril 10 mg Tablets**

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

### **1. WHAT NICORIL IS AND WHAT IT IS USED FOR**

Nicoril 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.

Nicoril 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 NICORIL**

#### **Do not take Nicoril:**

- 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 Nicoril.

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 Nicoril and contact your doctor immediately.

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 Nicoril:

- 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 medical products that may increase potassium levels.
- If you have heart problems such as heart failure.
- If you have glucose 6 Phosphate Deshydrogenase deficiency.

### **Children**

- Nicoril is not recommended in children .

### **Other medicines and Nicoril**

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

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

- Medicine 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).
- Medicines for depression.
- Aspirin(acetylsalicylic acid).

### **Nicoril with alcohol**

Nicorandil may lower your blood pressure. If you drink alcohol while you are treated with Nicoril, 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**

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

### **3. HOW TO TAKE NICORIL**

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.

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 tablet of 10 mg can be divided into equal doses.

For the tablet of 20 mg, 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 Nicoril 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 straight away talk to your doctor.

#### **If you take more Nicoril than you should**

If you take more Nicoril 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 Nicoril**

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 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), 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).
- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.

**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
- 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 Yellow Card Scheme, Website: [www.mhra.gov.uk/yellowcard](http://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 NICORIL**

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 blister.  
Use the blister 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 protect the environment.

## **6. CONTENT OF THE PACK AND OTHER INFORMATION**

### **What Nicoril 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 Nicoril looks like and contents of the pack:**

Nicoril 10 mg tablets are white, round, scored on one side and embossed with '10' on the other side.

Nicoril 20 mg tablets are white, round, scored on one side and embossed with '20' on the other side.

Nicoril is available in blister packs. Each blister contains 10 tablets.

Nicoril 10 mg: the blisters are packed in cartons of 20 and 60 tablets

Nicoril 20 mg: the blisters are packed in cartons of 60 tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer:**

#### Marketing Authorisation Holder

Rivopharm UK Ltd

30th Floor, 40 Bank Street, Canary Wharf, London, E14 5NR, UK

#### Manufacturer

Laboratories BTT, Z.I. de Krafft, 67 150 ERSTEIN, France

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