

INFORMATION FOR THE USER

IKOREL 10mg and 20mg Tablets

Nicorandil

Read all of this leaflet carefully before you start taking this medicine

- 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. 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 side effects not listed in this leaflet

In this leaflet:

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

1 What Ikorel is and what it is used for

The name of your medicine is Ikorel Tablets (called Ikorel in this leaflet). Ikorel 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

Ikorel is used to stop and treat long-term chest pain (angina).

2 What you need to know before you take Ikorel

Do not take this medicine and tell your doctor if:

- You are allergic (hypersensitive) to nicorandil or any of the other ingredients of Ikorel (listed in Section 6 below). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- You have low blood pressure (signs include feeling dizzy, light-headed or faint)
- You have a heart problem where it is damaged and cannot pump enough blood around the body
- You have heart failure (signs include shortness of breath, swollen ankles and legs, and feeling tired)

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 Ikorel.

Warnings and Precautions

Take special care with Ikorel

Check with your doctor or pharmacist before taking your medicine if:

- You have been told by your doctor that you have a low blood volume or low systolic blood pressure
- You have recently had a heart attack
- You have a build up of fluid in the lungs (pulmonary oedema)
- You have mouth ulcers
- You have bowel disease as it may get worse with Ikorel

When taking Ikorel there is an increased risk that you may develop ulceration in different parts of your body, including your eyes and the gastro-intestinal tract (gut). In some cases ulcers in the gut can rupture to cause serious bleeding. If you notice any signs of ulceration, you should seek immediate medical advice, as you will need to stop taking Ikorel (see section 4 possible side effects).

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

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Ikorel can affect the way some other medicines work. Also some medicines can affect the way Ikorel works.

In particular, do not take this medicine, and tell your doctor if you are taking:

- Medicines for impotence such as sildenafil, tadalafil or vardenafil.
- Tell your doctor if you are taking any of the following:
- Medicines that widen the blood vessels such as hydralazine, minoxidil or nitroprusside (vasodilators)
 - Medicines for high blood pressure
 - Medicines for depression
 - Types of medicines called corticosteroids
 - Medicines that increase the amount of potassium in your blood

- Aspirin (acetylsalicylic acid) used to treat minor aches and pains or to reduce fever

Children

Ikorel is not recommended for use in children.

Taking Ikorel with food and drink

Do not drink alcohol while you are taking Ikorel.

Pregnancy and breast-feeding

Talk to your doctor before taking this medicine if you are pregnant, might become pregnant, or think you may be pregnant.

You should not breast-feed if you are taking Ikorel. This is because small amounts may pass into mothers' milk.

If you are breast-feeding or planning to breast-feed, talk to your doctor or pharmacist before taking any medicine.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding

Driving and using machines

You may feel dizzy while taking this medicine. If this happens, do not drive or use any tools or machines.

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

3 How to take Ikorel

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

You should not take the tablets, which are included in the pack to protect Ikorel Tablets from moisture. If you do accidentally take any of these tablets, they should do you no harm, but you should tell your doctor straight away.

Taking this medicine

- Take this medicine by mouth
- Swallow the tablets whole with a drink of water. Do not crush or chew the tablets
- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor

How much to take

- The usual dose is 10mg or 20mg taken in the morning and evening.
- Your doctor might increase this to 30mg twice a day if necessary.
- The maximum dose is 40mg twice a day.
- If you have a tendency to get headaches, your doctor may start you on a lower dose of 5mg (half a 10mg tablet) twice a day.
- If taking a 5mg dose, discard the remaining half of the 10mg tablet
- Do not keep the second half of the tablet for future use.

If you take more Ikorel 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 taken. The following effects may happen: you may feel dizzy or weak or have difficulty in breathing or wheezing.

If you forget to take Ikorel

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 Ikorel

Keep taking Ikorel until your doctor tells you to stop. Do not stop taking Ikorel 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, Ikorel can cause side effects, although not everybody gets them.

Stop taking Ikorel and see a doctor or go to a hospital straight away if you have the following side effects:

Uncommon

- Red and lumpy skin rash, swollen eyelids, face, lips, mouth or tongue, itching, difficulty breathing or swallowing. This could be an allergic reaction (angioedema).

Rare

- Burning pain in the middle or upper stomach between meals, bloating, heartburn, vomiting, these can be signs of ulcers in the stomach or gut.

Severe ulcers can cause blood in your stools, vomiting, weight loss and severe abdominal pain

Very rare

- Yellowing of your skin or eyes (which may be signs of liver problems)
 - Red, itchy, swollen, watery eyes or painful eyes with blurred vision.
- This could be a symptom of eye ulceration.

Tell a doctor straight away if any of the following side effects trouble you:

Common

- Increased or fast heart-beat

Rare

- Blood in your stools or vomit, due to ulcers in the stomach or gut
- Ulcers in your mouth, or on your tongue
- Ulcers of the back passage, bleeding from the back passage
- Weight loss

Very rare

- Weakness, fatigue and a slow heart beat due to high levels of potassium in the blood

Frequency Unknown

- Ulcers of the genital tract
- Skin ulcers, possibly on the hands, legs, or feet
- Ulcers in the nasal passages
- Ulcers around a stoma (in those with an artificial opening for waste removal such as a colostomy or ileostomy)

Tell your doctor as soon as possible if you have any of the following side-effects:

Very Common (affects more than 1 in 10 people)

- Headache. These are more common when you first start taking Ikorel

Common (affects less than 1 in 10 people)

- Feeling dizzy or weak
- Feeling sick or being sick
- Flushing of the skin

Uncommon (affects less than 1 in 100 people)

- Feeling dizzy, lightheaded or fainting (due to low blood pressure)
- Pain in your muscles

Rare (affects less than 1 in 1000 people)

- Skin rashes
- Mouth ulcers

Very Rare (affects less than 1 in 10,000 people)

- Stomach pain
- Hyperkalaemia (high potassium levels in your blood)

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Ikorel

Keep this medicine in a safe place where children cannot see or reach it. Do not use Ikorel 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. Keep the blister strip in the outer carton in order to protect from moisture. If taking half a tablet, do not keep the second half of tablet for a later dose. Discard the remaining tablet. Each blister strip should be used within 30 days of opening. 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 Ikorel Tablets contain

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

What Ikorel Tablets look like and contents of the pack

Ikorel Tablets are white, round, scored with IK10 or IK20 engraved on the tablets. They are supplied in cartons of 60 tablets.

Parallel Product Authorisation Holder

IMED Healthcare Ltd
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15, Ireland

Manufacturer

Sanofi Winthrop Industrie
56 route de Choisy-au-Bac
60205 Compiègne Cedex
France

Repackaged by:

Cast Healthcare Ltd
Unit B6 The Business Centre
5-7 Tobermore Road
Draperstown
Northern Ireland
BT45 7AG

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Manufacturer

Sanofi Winthrop Industrie
56 route de Choisy-au-Bac
60205 Compiègne Cedex
France

Repackaged by:

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Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15, Ireland

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