**PACKAGE LEAFLET: INFORMATION FOR THE USER**

# IKOREL 10mg Tablets
# IKOREL 20mg 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 Ikorel is and what it is used for

Ikorel contains the active substance 'nicorandil'. This belongs to a group of medicines called 'potassium channel activators'.

Ikorel 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' or 'calcium antagonists'.

Ikorel 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.

## 2. What you need to know before you take Ikorel

**Do not take Ikorel if:**

- you are allergic to nicorandil or any of the other ingredients of this medicine (listed in section 6).
- you have severe low blood pressure ('hypotension').
- you have heart problems such as cardiogenic shock, or left ventricular failure with low filling pressure or cardiac decompensation.
- you are taking medicines to treat erectile dysfunction (such as sildenafil, tadalafil, vardenafil) or medicines to treat 'pulmonary hypertension' (such as riociguat). Your blood pressure may
- be affected if these medicines are taken with Ikorel.
- you have a low blood volume.
- you have a build-up of fluid in the lungs ('pulmonary oedema').

Do not take Ikorel 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**

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, 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 Ikorel. 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 Ikorel if:
- you have low blood pressure.
- you have low blood potassium levels and are taking potassium supplements.
- you have kidney problems or are taking other medicines that may increase potassium levels.
- you have heart problems such as heart failure.
- you have a genetic condition called 'glucose 6 phosphate dehydrogenase deficiency'.

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

**Children**
Ikorel is not recommended for use in children.

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

**Do not take this medicine, and talk to your doctor** if you are taking any of the following:
- medicines for erectile dysfunction 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** before taking Ikorel, 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 and non-inflammatory steroidal drugs such as ibuprofen. If taken with Ikorel you may be more likely to get ulcers.
- medicines for depression.
- aspirin (acetylsalicylic acid).

**Tell your doctor** before taking Ikorel if you are taking any of the medicines above.

**Ikorel with alcohol**
Nicorandil may lower your blood pressure. If you drink alcohol while being treated with Ikorel, your blood pressure may become even lower.

**Pregnancy and 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 if you are pregnant.
It is not known whether nicorandil passes into your breast-milk. You should not breast-feed while you are taking this medicine.

**Driving and using machines** Ikorel may make you feel dizzy or weak. If this happens, do not drive or use any tools or machines.

**Ikorel contains**
This medicine contains less than 1 mmol sodium (23mg) per dosage unit that is to say essentially 'sodium free'.

## 3. How to take Ikorel

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

**How much to take**
The recommended dose is 10mg twice day.
- In case you get headaches, your doctor may give you a lower dose of 5 mg twice a day for the first 2 to 7 days.
- Your doctor may increase your dose up to 20mg, twice a day. This will depend on your needs, response and tolerance to treatment.
-

**Taking this medicine**
- Take one dose in the morning and one in the evening.
- Swallow the tablet (oral use).
- Do not take the tablet out of the blister strip until you are about to take it.
- 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.

A larger desiccant capsule corresponding to a 'drying agent' is clearly marked at one end of each blister strip. It is to protect Ikorel tablets from moisture. Do not swallow this desiccant capsule. If you do accidentally take a desiccant capsule, talk to your doctor straight away. They should not harm you.

**If you take more Ikorel than you should**
If you take more Ikorel tablets than you should, or if a child swallows any of the tablets, talk to a doctor or go to hospital straight away. Take the medicine pack with you. You may feel dizzy or weak – signs of low blood pressure. You may also feel your heart beating irregularly and faster.

**If you forget to take Ikorel**
If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for your next dose, skip the missed 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.

**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 (inflammation or ulcer) with parts of the eye called the 'cornea' and 'conjunctiva' (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 HPRA Pharmacovigilance Website: www.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 out of the sight and reach of children.

Do not use this medicine 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 store above 25°C. Store in the original packaging in order to protect from moisture. After opening, each blister strip should be used within 30 days at above mentioned storage conditions.

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. Contents of the pack and other information

### What Ikorel contains

The active substance is nicorandil. Each tablet contains 10 mg or 20 mg of the active substance, nicorandil.

The other ingredients are maize starch, croscarmellose sodium, stearic acid (E570) and mannitol (E421).

### What Ikorel looks like and contents of the pack

Ikorel is an off-white, round tablet with facetted edge, scored on one side, and with inscription "IK10" or "IK20" on the other side.

Ikorel 10 mg tablets: the tablet can be divided into equal doses.
Ikorel 20 mg tablets: the scoreline is only to facilitate for ease of swallowing and not to divide into equal doses.

A larger desiccant capsule corresponding to a 'drying agent' is clearly marked at one end of each blister strip. It is to protect Ikorel tablets from moisture. The desiccant capsule must not be swallowed.

Pack sizes available are 30 or 60 tablets.
Not all pack sizes may be marketed.

### Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
sanofi-aventis Ireland Ltd. T/A SANOFI, Citywest Business Campus,
Dublin 24
Tel: 01 403 5600
Fax: 01 403 5687
email: IEmedinfo@sanofi.com

Manufacturer
Opella Healthcare International SAS 56, Route de Choisy
60200 Compiegne – France

**This medicinal product is authorised in the Member States of the EEA under the following names:**
France: IKOREL
Ireland: IKOREL
The Netherlands: IKOREL 10mg
United Kingdom: IKOREL

**This leaflet was last revised in August 2021.**