

Leaflet Details

Licence Number: PPA 1562/033/001/002 Ikorel Tablets 10mg/ Ikorel Tablets 20mg

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Text Free Border: 5mm (around edge & between columns)

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Ikorel Tablets 10mg/ Ikorel Tablets 20mg (Front & Back)

This is the final mock-up.

This leaflet has been user tested.

Ikorel[®] Tablets 10mg/ Ikorel[®] Tablets 20mg

(nicorandil)

Patient Information Leaflet

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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

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

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

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

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 tablet 10mg tablet
- * Do not keep the second half of the tablet for future use.

Children

Ikorel is not recommended in children.

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).

Very Rare

- * Yellowing of your skin or eyes (which may be signs of liver problems)

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(nicorandil)

Patient Information Leaflet (continued)

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 of the back passage, bleeding from the back passage

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)

Frequency unknown

- * Red, itchy, swollen, watery eyes or painful eyes with blurred vision

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)
- * Mouth ulcers
- * Pain in your muscles

Rare (affects less than 1 in 1000 people)

- * Skin rashes

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

- * Stomach pain

Talk to your doctor or pharmacist if any of the side effects gets serious or lasts longer than a few days, or if you notice any side effects not listed in this leaflet.

5 How to store this 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.

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 corn starch, croscarmellose sodium, stearic acid, 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.

The Parallel Product Authorisation Holder is:

LTT Pharma Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

Repackaged by:

Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

The manufacturer is:

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

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Blind or partially sighted?

Is this leaflet hard to see or read?

Phone LTT Pharma Limited,

Tel: +44 (0)1527 505414 for help.