

Ikorel(R)

(I-cor-(r)el)

Nicorandil (ni-cor-(r)an-dil)

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about Ikorel.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Ikorel is used for

Ikorel belongs to a group of medicines called "potassium channel openers". This means it increases the exit of potassium from certain muscle cells, particularly those found in arteries. This widens the arteries and reduces the workload required by the heart to pump the blood.

In addition, Ikorel has a "nitrate" property, which relaxes smooth muscle in the blood vessels, particularly in the veins.

Ikorel is used to treat chronic stable angina pectoris (chest pain). It works by widening blood vessels and increases blood supply to heart muscle.

Your doctor, however, may prescribe Ikorel for another purpose.

Ask your doctor if you have any questions about why it has been prescribed for you.

This medicine is only available with a doctor's prescription.

This medicine is not addictive.

Before you take Ikorel

When you must not take it

Do not take Ikorel if:

- * **you have ever had an allergic reaction to:**
 - nicorandil
 - nicotinic acid
 - nicotinamide
 - any of the ingredients listed at the end of this leaflet.

Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

- * **you have a low blood pressure (which could make you feel faint, weak or dizzy, especially when you stand up suddenly)**
- * **you suffer from any other type of serious heart diseases**
- * **you have been prescribed a phosphodiesterase 5 inhibitor by your doctor (medicines used to treat impaired sexual function, e.g. sildenafil**

(Viagra(R)), tadalafil (Cialis(R)), vardenafil (Levitra(R))

- * **the blister in which the tablets are stored has been open for more than 30 days**

Do not take it after the expiry date (EXP) printed on the pack.

If you take it after the expiry date has passed, it may not work as well.

Do not take it if the packaging is torn or shows signs of tampering.

Do not give Ikorel to a child.

There is no experience with its use in children.

Before you start to take it

Tell your doctor if you have allergies to:

- any other medicines
- any of the ingredients listed at the end of this leaflet
- any other substances, such as foods, preservatives or dyes.

Tell your doctor if you are pregnant or intend to become pregnant.

Your doctor will discuss the risks and benefits of taking it if you are pregnant.

Tell your doctor if you are breastfeeding or planning to breastfeed.

It is not known whether nicorandil passes into breast milk, hence it is recommended that you do not breastfeed while taking Ikorel. Your doctor will discuss the risks and

benefits of taking it if you are breastfeeding.

Tell your doctor if you have or have had any medical conditions, especially the following:

- * **liver disease**
- * **renal disease**
- * **low blood pressure (which can make you feel faint, weak or dizzy, especially when you stand up suddenly)**
- * **other types of serious heart diseases**
- * **mouth, stomach or skin ulcers**

If you have not told your doctor or pharmacist about any of the above, tell them before you take Ikorel.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food store.

Some medicines may be affected by Ikorel or may affect how well it works. These include:

- * phosphodiesterase 5 inhibitors (e.g. Viagra(R), Cialis(R), Levitra(R)) - medicines often used to treat impaired sexual function
- * other vasodilators - medicines used to widen blood vessels
- * tricyclic antidepressants (e.g. Tryptanol(R), Tofranil(R), Imipramin(R), Sinequan(R), Allegron(R), Surmontil(R), Pertofran(R), Prothiaden(R), Anafranil(R), etc) - medicines often used to treat depression
- * other nitrates - medicines used to treat angina
- * antihypertensive drugs
- * corticosteroids (e.g. prednisone or cortisone)

Ikorel may also increase the effects of alcohol.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking Ikorel.

You may need to use different amounts of your medicine, or take different medicines. Your doctor or pharmacist will advise you.

How to take it

How much to take

The standard adult dose of Ikorel is 10 mg to 20 mg twice a day. A lower starting dose (e.g. 5 mg twice a day) may be needed in some patients.

Your doctor may have prescribed a different dose.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Ikorel may not work as well and your problem may not improve.

How to take it

Swallow the tablet with a full glass of water.

When to take it

Take Ikorel in the morning and in the evening, either with or without food.

Take Ikorel at about the same time each day.

Taking your tablets at the same time each day will have the best effect. It will also help you remember when to take the tablets.

If you are not sure when to take it, ask your doctor or pharmacist.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

Do not stop taking your medicine or change the dose of your medicine

unless you are told to do so by your doctor.

Ask your doctor or pharmacist if you are not sure how long to take the medicine for.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to.

Do not take a double dose to make up for the dose you have missed.

If there is still a long time to go before your next dose, take it as soon as you remember, and then go back to taking it as you would normally.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for hints.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764766), or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much Ikorel.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much Ikorel, you will probably feel light-headed or dizzy, or your heart may beat faster than normal.

While you are taking it

Things you must do

Tell all the doctors, dentists and pharmacists who are treating you

that you are taking Ikorel.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Ikorel.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking this medicine.

If you become pregnant while you are taking this medicine, tell your doctor or pharmacist immediately.

Things you must not do

Do not take more than the recommended dose unless your doctor tells you to.

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not use this medicine to treat any other complaints unless your doctor tells you to.

Do not stop taking Ikorel, or lower the dosage, without checking with your doctor.

Your doctor may want you to gradually reduce the amount you are using before stopping completely.

Do not stop taking your tablets because you are feeling better, unless advised by your doctor or pharmacist.

Things to be careful of

Be careful driving or operating machinery until you know how Ikorel affects you.

Ikorel may cause dizziness or light-headedness in some people. Make sure you know how you react to it before you drive a car, operate machinery, or do anything else that could be dangerous if you feel dizzy. Do not drive if this occurs.

The effects of alcohol could be made worse while taking Ikorel. It is not recommended that you drink alcohol while taking Ikorel.

If you feel light-headed, dizzy or faint, be careful when getting up from a sitting or lying position.

Get up slowly. This may help when getting out of bed or standing up.

Side effects

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor or pharmacist has weighed the risks of using this medicine against the benefits they expect it will have for you.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- * headache
- * dizziness and light-headedness, especially when getting up from a sitting or lying down position
- * tiredness, drowsiness
- * cough
- * nausea, vomiting, indigestion
- * diarrhoea
- * constipation
- * stomach ache
- * flushing, sweating
- * loss of appetite, weight loss
- * fever
- * leg, neck, back, chest or muscular pain, pain in the arm or general pain
- * trouble sleeping
- * nervousness
- * depression
- * itching
- * double vision
- * nose bleed

The most common side effect of Ikorel is headache. This usually occurs in the first few days after you start taking Ikorel and generally does not last long.

These are mild side effects of this medicine and usually short-lived.

Tell your doctor or pharmacist immediately if you notice any of the following:

- * high blood pressure
- * fast or irregular heart beats
- * swelling of the face, hands, ankles or feet
- * difficulty in breathing or shortness of breath
- * tingling or numbness of the hands or feet
- * rash
- * ringing or other persistent noise in the ears
- * persistent mouth ulcers or genital, anal or skin ulcers

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- * swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing

These may be serious side effects of Ikorel. You may need urgent medical attention. Serious side effects are uncommon.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may occur in some consumers.

Ask your doctor or pharmacist to answer any questions you may have.

After using it

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

Storage

Ikorel tablets must be protected from moisture. This is the reason why Ikorel tablets are packed with a desiccant.

Keep Ikorel tablets in the blister pack until it is time to take them.

If you take the tablets out of the blister pack they may not keep well.

Any unused tablets held for 30 days after opening the blister strip should be discarded.

Keep the medicine in a cool, dry place where the temperature stays below 25 degrees C.

Do not store it or any other medicine in the bathroom, near a sink, or on a windowsill. Do not leave it in the car.

Heat and damp can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking Ikorel, or the medicine has passed its expiry date, ask your pharmacist what to do with any tablets that are left over.

Return any unused medicine to your pharmacist.

Product description

What it looks like

Ikorel tablets are available in two strengths:

- * 10 mg tablet: round, scored, white tablet, marked "IK/10" on one side and plain on the other side.
- * 20 mg tablet: round, scored, white tablet, marked "IK/20" on one side and plain on the other side.

Ikorel 10 mg and 20 mg tablets are available in boxes of 60 tablets.

Ingredients

Active Ingredient:

Ikorel tablets contain either 10 mg or 20 mg of nicorandil per tablet as the active ingredient.

Inactive Ingredients:

Ikorel tablets also contain the following inactive ingredients:

- * maize starch
- * croscarmellose sodium
- * stearic acid
- * mannitol

There are no dyes, sucrose, lactose, gluten or preservatives in Ikorel tablets.

Sponsor

Ikorel is supplied in Australia by:
sanofi-aventis australia pty ltd
12-24 Talavera Road
Macquarie Park NSW 2113

Ikorel is supplied in New Zealand by:
sanofi -aventis new zealand limited
Level 8, James and Wells Tower
56 Cawley Street
Ellerslie
Auckland

This leaflet was prepared in November 2008.

Australian Register Number(s)
10mg tablets: AUST R 56845
20mg tablets: AUST R 56846

(R) Registered Trademark