

IKOREL Tablets

Nicorandil

Consumer Medicine Information

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 IKOREL 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 medications 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 may have prescribed IKOREL for another reason.

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

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

Before you take IKOREL

When you must not take it

Do not take IKOREL if:

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

Some of the symptoms of an allergic reaction may include wheezing, difficulty in breathing, itching, runny nose, skin rash.

- 2. you have a low blood pressure (which could make you feel faint, weak or dizzy, especially when you stand up suddenly)**
- 3. you suffer from any other type of serious heart diseases**
- 4. you have been prescribed a phosphodiesterase 5 inhibitor (e.g. sildenafil, tadalafil, vardenafil) (drugs used to treat impaired sexual function) by your doctor**
- 5. the blister in which the tablets are stored has been open for more than 30 days**

- 6. the expiry date on the pack has passed.**

If you take this medicine after the expiry date has passed it may have no effect at all, or worse, an entirely different effect.

- 7. the packaging is torn or shows signs of tampering**

If you are not sure whether you should start taking IKOREL, talk to your doctor.

Before you start to take it

Tell your doctor if you have any allergies to:

- * any other medicines
- * any other substances such as foods, preservatives or dyes

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

However, if you need to take IKOREL during your pregnancy, your doctor will discuss with you the benefits and risks of using it.

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

It is recommended that you do not breastfeed while taking IKOREL, as it is not known whether IKOREL passes into the breast milk.

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

- * liver 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

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking IKOREL.

Taking other medicines

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

There may be interference between IKOREL and some other medicines, including:

- * phosphodiesterase 5 inhibitors (e.g. sildenafil, tadalafil, vardenafil) - medicines used to treat impaired sexual function
- * other vasodilators, medicines used to widen blood vessels
- * tricyclic antidepressants (such as Tryptanol, Tofranil, Imipramin, Sinequan, Allegron, Surmontil, Pertofran, Prothiaden, Anafranil) medicines used to treat depression
- * other nitrates - medicines used to treat angina
- * alcohol
- * other antihypertensive drugs

These medicines may be affected by IKOREL or may affect how well it works. You may need different amounts of your medicine or you may need to take different medicines. Your doctor will advise you.

How to take IKOREL

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box ask your doctor or pharmacist for help.

How to take it

Swallow IKOREL tablets with a full glass of water, in the morning and in the evening either with or without food.

How much to take

Your doctor will tell you how much IKOREL to take. Take the amount your doctor tells you to.

The usual adult dose of IKOREL is between 10mg and 20mg twice a day.

How long to take it

Continue to take your tablets for as long as your doctor recommends. Do not stop taking them even if you begin to feel better, unless you are told to do so by your doctor. Never change the dose of your medicine without talking to your doctor first.

If you forget to take it

If you forget to take IKOREL, and it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, then go back to taking it as you would normally.

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

If you have trouble remembering to take IKOREL, ask your pharmacist for some hints.

If you take too much (Overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) or go to Accident and Emergency at your nearest hospital if you think that you, or anyone else, has taken too much IKOREL even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep these telephone numbers handy.

If you take too many tablets you may feel lightheaded, dizzy and your heart may beat faster than normal.

While you are taking IKOREL

Things you must do

Take IKOREL exactly as your doctor has prescribed.

Try not to miss any doses and continue to take the medicine even if you feel well.

Tell your doctor immediately if you become pregnant while taking IKOREL.

Tell all doctors, dentists and pharmacists who are treating you that you are using IKOREL, especially if you are being started on any new medicines.

Things you must not do

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

Do not stop taking IKOREL, or lower the dosage, even if you are feeling better, without checking with your doctor.

If you stop taking IKOREL suddenly, your condition may worsen or your chance of getting an unwanted side effect may increase. To prevent this your doctor may gradually reduce the amount of IKOREL you take each day before stopping completely.

Do not use IKOREL to treat any other medical complaints unless your doctor tells you to.

Things to be careful of

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

IKOREL may cause dizziness and light-headedness in some people. Make sure you know how you react to IKOREL before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs do not drive. If you drink alcohol, dizziness or light-headedness may be worse.

If IKOREL makes you feel light-headed, dizzy or faint, be careful when getting up from a sitting or lying position. Getting up slowly may help.

Side Effects

Tell your doctor as soon as possible if you do not feel well while taking IKOREL.

All medicines have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Common side effects

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.

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

- * stomach ache
- * tiredness
- * back, chest and muscular pain
- * high blood pressure
- * fast or irregular heart beats
- * flushing
- * nausea
- * indigestion
- * dizziness
- * cough and difficulty in breathing

Less common side effects

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

- * feeling unwell
- * swelling of the face, hand, ankles or feet
- * fever
- * leg, neck, pain in the arm or general pain dizziness and light-headedness, especially when getting up from a sitting or lying down position.
- * vomiting

- * loss of appetite
- * diarrhoea
- * constipation
- * trouble sleeping
- * nervousness
- * depression
- * drowsiness
- * tingling or numbness of the hands or feet
- * rash
- * sweating
- * itching

Rare side effects

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

- * ringing or other persistent noise in the ears
- * persistent mouth ulcers

Other side effects not listed above may also occur in some patients.

Tell your doctor as soon as possible if you notice any other effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using IKOREL

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 tablets in a cool dry place where the temperature stays below 25 degrees C.

Do not store them or any other medicine in the bathroom or near a sink.

Do not leave them in the car or on window sills.

Heat and dampness 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 tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

Product Description

These tablets come in two strengths. Both are round, scored and white in colour.

The 10mg tablet is marked "IK/10" one side and plain on the reverse, while the 20mg is marked "IK/20" one side and plain on the reverse.

IKOREL(R) 10mg and 20mg tablets are available in packs of 60 tablets.

Ingredients

IKOREL(R) contains either 10mg or 20mg of nicorandil, as the active ingredient.

IKOREL(R) tablets also contain the following inactive ingredients:

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

There are no dyes, gluten or preservatives in IKOREL(R) tablets.

IKOREL(R) is supplied in Australia by:

Aventis Pharma Pty Ltd
12-24 Talavera Road
Macquarie Park NSW 2113

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IKOREL(R) 10mg tablet:
AUST R 56845

IKOREL(R) 20mg tablet:
AUST R 56846