

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using Ikorel?

Ikorel contains the active ingredient nicorandil. Ikorel is used to treat some forms of angina pectoris (chest pain). It works by widening blood vessels and increases blood supply to heart muscle. For more information, see Section [1. Why am I using Ikorel?](#) in the full CMI.

### 2. What should I know before I use Ikorel?

Do not use if you have ever had an allergic reaction to nicorandil or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section [2. What should I know before I use Ikorel?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Ikorel and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use Ikorel?

- 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
- Ikorel is swallowed whole with a full glass of water, in the morning and evening, with or without food.
- More instructions can be found in Section [4. How do I use Ikorel?](#) in the full CMI.

### 5. What should I know while using Ikorel?

<b>Things you should do</b>	<ul style="list-style-type: none"> <li>• Tell all the doctors, dentists and pharmacists who are treating you that you are taking Ikorel</li> <li>• If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Ikorel</li> <li>• If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking this medicine</li> <li>• If you become pregnant while you are taking this medicine, tell your doctor or pharmacist immediately</li> </ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>• Do not take more than the recommended dose unless your doctor tells you to</li> <li>• Do not give this medicine to anyone else, even if they have the same condition as you</li> <li>• Do not use this medicine to treat any other complaints unless your doctor tells you to</li> <li>• 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</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• Be careful driving or operating machinery until you know how Ikorel affects you.</li> <li>• Ikorel may cause dizziness or light-headedness in some people.</li> </ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"> <li>• It is not recommended that you drink alcohol while taking Ikorel as the effects of alcohol could be made worse while taking Ikorel</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Keep the medicine in a cool, dry place where the temperature stays below 25°C</li> <li>• Keep Ikorel tablets in the blister pack until it is time to take them. Ikorel tablets must be protected from moisture.</li> </ul>

For more information, see Section [5. What should I know while using \[insert medicine\]?](#) in the full CMI.

### 6. Are there any side effects?

Common side effects include: headache, dizziness and cough; Serious side effects include: rash, high blood pressure. Refer to the CMI for the complete list. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Ikorel.

**You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Ikorel.**

**Where to find information in this leaflet:**

- [1. Why am I using Ikorel?](#)
- [2. What should I know before I use Ikorel?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Ikorel?](#)
- [5. What should I know while using Ikorel?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why am I using Ikorel?

**Ikorel contains the active ingredient nicorandil.**

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 some forms of angina pectoris (chest pain). It works by widening blood vessels and increases blood supply to heart muscle.**

### 2. What should I know before I use Ikorel?

#### Warnings

**Do not use Ikorel if:**

- you are allergic to nicorandil, nicotinic acid, nicotinamide or 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.
- Always check the ingredients to make sure you can use this medicine.
- 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®), tadalafil (Cialis®), vardenafil (Levitra®))
- you have been prescribed any soluble guanylate cyclase stimulators e.g. riociguat (Adempas®)
- the blister in which the tablets are stored has been open for more than 30 days
- the expiry date has passed
- the packaging is torn or shows signs of tampering

#### Check with your doctor if you:

- have any allergies to any other medicine, any of the ingredients listed at the end of this leaflet, any other substances, such as foods, preservatives or dyes
- have or have had any other medical conditions, especially the following:
  - liver disease
  - renal disease
  - diverticular disease (a condition affecting the muscles of the bowel)
  - low blood pressure (which can make you feel faint, weak or dizzy, especially when you stand up suddenly)
  - other types of serious heart diseases
  - depression
  - glaucoma
  - hyperkalaemia (high potassium levels in the blood)
  - mouth, stomach or skin ulcers
- take any medicines for any other condition
- are pregnant or intend to become pregnant
- if you are breast feeding or planning to breastfeed
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During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

#### Pregnancy and breastfeeding

- 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

#### Use in children

Do not give Ikorel to a child. There is no experience with its use in children.

### 3. What if I am taking other medicines?

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

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

- phosphodiesterase 5 inhibitors (e.g. Viagra®, Cialis®, Levitra®) - medicines often used to treat impaired sexual function
- soluble guanylate cyclase stimulators (e.g. Adempas®)
- other vasodilators - medicines used to widen blood vessels
- tricyclic antidepressants (e.g. Endep®, Tofranil®, Sinequan®, Allegron®, Surmontil®, Prothiaden®, Anafranil®, etc) - medicines used to treat depression

- other nitrates - medicines used to treat angina
- medicines used to treat high blood pressure
- corticosteroids (e.g. prednisone or cortisone)
- aspirin or other Non Steroidal Anti-inflammatories (NSAIDS) e.g. ibuprofen, diclofenac

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Ikorel.**

## 4. How do I use Ikorel?

### 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.
- Follow the instructions provided and use Ikorel until your doctor tells you to stop. Do not stop taking the medicine till your doctor tells you to stop.

### When to take Ikorel

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

### How to take Ikorel

- Swallow the tablet with a full glass of water
- Take Ikorel at about the same time each day. Taking your tablets at the same time each day will have the best effect.

### If you forget to use Ikorel

Ikorel should be used regularly at the same time each day.

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

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

### If you use too much Ikorel

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

If you think that you have used too much Ikorel, you may need urgent medical attention.

### You should immediately:

- phone the Poisons Information Centre
- **(by calling 13 11 26 in Australia)**, or
- **(by calling 0800 764 766 in New Zealand)**, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

## 5. What should I know while using Ikorel?

### Things you should 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

### Call your doctor straight away if you:

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

### Things you should not do

Do not stop using this medicine suddenly

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

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.

### Driving or using machines

**Be careful before you drive or use any machines or tools 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

### Drinking alcohol

**Tell your doctor if you drink alcohol.**

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

### Looking after your medicine

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

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

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

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

in the bathroom or near a sink, or

in the car or on window sills.

Do not use this medicine after the expiry date.

Keep it where young children cannot reach it.

## When to discard your medicine

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

## Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"><li>headache</li><li>dizziness and light-headedness, especially when getting up from a sitting or lying down position</li><li>tiredness, drowsiness</li><li>cough</li><li>nausea, vomiting, indigestion</li><li>diarrhoea</li><li>constipation</li><li>stomach ache</li><li>flushing, sweating</li><li>loss of appetite, weight loss</li><li>fever</li><li>leg, neck, back, chest or muscular pain, pain in the arm or general pain</li><li>trouble sleeping</li><li>nervousness</li><li>depression</li><li>itching</li><li>double vision</li><li>nose bleed</li><li>skin abscess</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"><li>high blood pressure</li><li>fast or irregular heart beats</li><li>swelling of the face, hands, ankles or feet</li><li>difficulty in breathing or shortness of breath</li><li>tingling or numbness of the hands or feet</li><li>rash</li><li>ringing or other persistent noise in the ears</li><li>persistent mouth and tongue ulcers or genital, anal or skin ulcers</li><li>dark bowel motions and/or bloody diarrhoea</li></ul>	<b>Tell your doctor or pharmacist immediately if you notice any of the following</b>

Serious side effects	What to do
<ul style="list-style-type: none"><li>inflammation of the bowel wall (fever, vomiting and stomach pain or discomfort)</li><li>high potassium levels in the blood</li><li>nerve paralysis</li></ul>	
<b>Allergic reaction:</b> <ul style="list-style-type: none"><li>swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing</li></ul>	<b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems) (Australia) or the Centre for Adverse Reactions Monitoring (CARM) within the New Zealand Pharmacovigilance Centre <https://nzphvc.otago.ac.nz/reporting/> (New Zealand).

By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

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

### What Ikorel contains

<b>Active ingredient (main ingredient)</b>	either 10 mg or 20 mg of nicorandil
<b>Other ingredients (inactive ingredients)</b>	maize starch croscarmellose sodium stearic acid mannitol
<b>Potential allergens</b>	None

**Do not take this medicine if you are allergic to any of these ingredients.**

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

### What Ikorel looks like

10 mg tablet: round, scored, white tablet, marked "IK/10" on one side and plain on the other side. Pack size: 60 tablets (Aust R 56845).

20 mg tablet: round, scored, white tablet, marked "IK/20" on one side and plain on the other side. Pack size: 60 tablets (Aust R 56846).

**Who distributes Ikorel**

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,

56 Cawley Street Ellerslie

Auckland

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