

# IKOTAB

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## 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.

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### 1. Why am I using IKOTAB?

IKOTAB contains the active ingredient nicorandil. IKOTAB is used to treat chronic stable angina pectoris (chest pain or discomfort due to coronary heart disease). It works by widening blood vessels and increases blood supply to heart muscle. For more information, see Section [1. Why am I using IKOTAB?](#) in the full CMI.

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

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 IKOTAB?](#) in the full CMI.

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

Some medicines may interfere with IKOTAB 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 IKOTAB?**

- The standard adult dose of IKOTAB is 10 mg to 20 mg twice a day. A lower starting dose may be needed in some patients. Your doctor may have prescribed a different dose.
- IKOTAB 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 IKOTAB?](#) in the full CMI.

### **5. What should I know while using IKOTAB?**

#### **Things you should do**

- Tell all the doctors, dentists and pharmacists who are treating you that you are taking IKOTAB.
- If you are about to be started on any new

	<p>medicine, tell your doctor and pharmacist that you are taking IKOTAB.</p> <ul style="list-style-type: none"> <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 IKOTAB, or lower the dosage, without</li> </ul>

	checking with your doctor. Your doctor may want you to gradually reduce the amount you are using before stopping completely.
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• Be careful driving or operating machinery until you know how IKOTAB affects you.</li> <li>• IKOTAB may cause dizziness or light-headedness in some people.</li> </ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"> <li>• Be careful when drinking alcohol while you are taking this medicine.</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 IKOTAB tablets in the blister pack until it is time to take them. IKOTAB tablets must be protected from moisture.</li> </ul>

For more information, see Section [5. What should I know while using IKOTAB?](#) 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.

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.

# IKOTAB

**Active ingredient(s): Nicorandil**

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## **Consumer Medicine Information (CMI)**

This leaflet provides important information about using IKOTAB. **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 IKOTAB.**

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

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

## **1. Why am I using IKOTAB?**

**IKOTAB contains the active ingredient nicorandil.**

IKOTAB belongs to a group of medicines called potassium channel activators. This medicine works by widening blood vessels and increasing blood supply to the heart muscle.

**IKOTAB is used to treat chronic stable angina pectoris (chest pain or discomfort due to coronary heart disease).**

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

## **2. What should I know before I use IKOTAB?**

### **Warnings**

#### **Do not use IKOTAB if:**

- you are allergic to nicorandil or any of the ingredients listed at the end of this leaflet. Some symptoms of an allergic reaction include shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin.

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 type of medicine called a 'phosphodiesterase 5 inhibitor' - these medicines are used to treat impaired sexual function
- you have been prescribed any soluble guanylate cyclase stimulators e.g. riociguat
- 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

**If you are not sure whether you should start taking this medicine, talk to your doctor.**

### **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
  - kidney 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

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

Do not take this medicine if you are pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not breast-feed if you are taking this medicine.

## **Use in children**

Do not give this medicine to children.

Safety and effectiveness in children have not been established.

### **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 and IKOTAB may interfere with each other. These include:

- Phosphodiesterase 5 inhibitors - medicines often used to treat impaired sexual function
- soluble guanylate cyclase stimulators
- other vasodilator medicines, used to widen blood vessels
- tricyclic antidepressants - used to treat depression
- other nitrates - medicines used to treat angina (chest pain)
- medicines used to treat high blood pressure
- corticosteroid medicines
- aspirin or other non-steroidal anti-inflammatories (NSAIDs) e.g. ibuprofen, diclofenac

These medicines may be affected by IKOTAB or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

## 4. How do I use IKOTAB?

### How much to take

- The standard adult dose of IKOTAB is 10 mg to 20 mg twice a day. A lower starting dose may be needed in some patients.
- Your doctor may have prescribed a different dose.
- Follow the instructions provided and use IKOTAB until your doctor tells you to stop. Do not stop taking the medicine till your doctor tells you to stop.

### When to take IKOTAB

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

### How to take IKOTAB

- Swallow the tablet with a full glass of water
- Take IKOTAB 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 IKOTAB**

IKOTAB 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 IKOTAB**

If you take too much IKOTAB, 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 IKOTAB, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## **5. What should I know while using IKOTAB?**

### **Things you should do**

- Tell all the doctors, dentists and pharmacists who are treating you that you are taking IKOTAB.
- If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking IKOTAB.
- If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking this medicine.

It may affect other medicines used during surgery.

- Keep all of your doctor's appointments so that your progress can be checked.

### **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 IKOTAB, 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.

If this problem continues or gets worse, talk to your doctor.

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how IKOTAB affects you.**

IKOTAB 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.**

Be careful when drinking alcohol while you are taking this medicine.

IKOTAB may increase the effects of alcohol.

## **Looking after your medicine**

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

Keep IKOTAB 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.

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.

## **Keep it where young children cannot reach it.**

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

## **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**

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"><li>• headache headaches usually occur when you begin to take IKOTAB, and generally do not last long.</li><li>• dizziness and light headedness, especially when getting up from</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

<b>Less serious side effects</b>	<b>What to do</b>
<p>a sitting or lying down position</p> <ul style="list-style-type: none"> <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>	

## 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 ulcers or genital, anal or skin ulcers</li><li>● dark bowel motions and/or bloody diarrhoea</li><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>Tell your doctor as soon as possible if you notice any of the following:</b>

<b>Serious side effects</b>	<b>What to do</b>
<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). 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 IKOTAB contains**

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

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

## **What IKOTAB looks like**

IKOTAB 10 mg tablets are round and white scored on one side and marked '10' on the other side. (AUST R 218690).

IKOTAB 20 mg tablets are round and white scored on one side and bearing the inscription '20' on the other side. (AUST R 218689).

They are available in blister packs of 60 tablets. Each blister strip contains a desiccant.

## **Sponsor**

**Viatris Pty Ltd**

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