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## Consumer Medicine Information

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### What is in this leaflet

This leaflet answers some common questions about Ikotab. 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.

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### What Ikotab is used for

Ikotab contains nicorandil as the active ingredient and is used to treat chronic stable angina pectoris i.e. chest pain.

It works by widening blood vessels and increases blood supply to heart muscle.

**Ask your doctor if you have any questions about why it has been prescribed for you.** Your doctor may have prescribed it for another purpose.

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

It is not addictive.

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### Before you take it

#### *When you must not take it*

**Do not take Ikotab if you have ever had an allergic reaction to:**

- nicorandil, nicotinic acid or nicotinamide
- any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty in breathing; swelling of the face, lips, tongue or any other parts of the body; rash, itching or hives on the skin.

**Do not take Ikotab if:**

- you have 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 e.g. sildenafil and tadalafil.
- **the blister strip in which the tablets are stored has been open for more than 30 days.**

**Do not give Ikotab to children.**

There is no experience with its use in children.

**Do not take it after the expiry date 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.**

#### *Before you start to take it*

**Tell your doctor if you are allergic to any other medicines or any foods, dyes or preservatives.**

**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 breast feeding or planning to breast feed.**

It is not recommended for use during breast feeding as it is not known whether nicorandil passes into breast milk.

**Tell your doctor if you have or have had any of the following medical conditions:**

- kidney or 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
- mouth, stomach or skin ulcers.

**If you have not told your doctor about any of the above, tell them before you start to take Ikotab.**

#### *Taking other medicines*

**Tell your doctor 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 Ikotab or may affect how well it works. These include:

- phosphodiesterase 5 inhibitors e.g. sildenafil – medicines often used to treat impaired sexual function
- vasodilators – used to widen blood vessels
- tricyclic antidepressants – medicines often used to treat depression
- nitrates – medicines used to treat angina
- antihypertensive drugs
- corticosteroids - e.g. prednisone or cortisone.

Ikotab may also increase the effects of alcohol.

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

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

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### How to take it

#### *How much to take*

Your doctor will tell you how much Ikotab to take.

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

#### *When to take it*

**Take this medicine in the morning and in the evening, at about the same time each day either with or without food.**

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 Ikotab, or change the dosage, without checking with your doctor.**

Your doctor may want you to gradually change the amount you are taking before stopping completely.

#### *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.**

**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 take too much (overdose)*

**Immediately telephone your doctor or the Poisons Information Centre (telephone Australia 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much Ikotab.**

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

You may need urgent medical attention.

Symptoms of overdose may include feeling light-headed or dizzy and a faster than normal heart beat.

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### While you are taking it

#### *Things you must do*

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

**Tell your doctor if you become pregnant while you are taking this medicine.**

#### *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 Ikotab, or change the dosage, without checking with your doctor.**

Your doctor may want you to gradually change the amount you are taking before stopping completely.

#### *Things to be careful of*

**Be careful driving or operating machinery 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.

Dizziness and light headedness can be made worse when this medicine is taken with

alcohol. It is recommended that you do not drink alcohol while taking Ikotab.

**Be careful when getting up from a sitting or lying position if you feel light-headed, dizzy or faint.**

It may help to get up slowly when getting out of bed or standing up.

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## Side effects

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**Tell your doctor as soon as possible if you do not feel well while you are taking Ikotab.**

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

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

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

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

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

- high blood pressure
- fast or irregular heart beat
- 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 symptoms:**

- allergic type reactions e.g. skin rash, itching and difficulty breathing, wheezing or coughing.

This is a serious side effect of Ikotab. 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, even if you think the problems are not connected with this medicine and are not referred to in this leaflet.**

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

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

You may not experience any of them.

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## After taking it

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### Storage

**Store below 25°C in the original package. Keep Ikotab tablets in the blister strip until it is time to take them.**

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

**Discard 30 days after opening the blister strip.**

Ikotab tablets must be protected from moisture.

**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

**Return any unused medicine to your pharmacist.**

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## Product description

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### What it looks like

Ikotab tablets come in two strengths, 10 mg and 20 mg.

**10 mg:** Round white tablets, scored on one side and marked with '10' on the other side. Blister packs of 20 or 60 tablets. Each blister strip also contains a desiccant.

**20 mg:** Round white tablets, scored on one side and marked with '20' on the other side. Blister packs of 20 or 60 tablets. Each blister strip also contains a desiccant.

(Note: Not all pack sizes or strengths may be marketed.)

### Ingredients

#### Active Ingredient:

Each tablet contains either 10 mg or 20 mg of nicorandil.

#### Inactive ingredients:

- pregelatinised maize starch
- croscarmellose sodium
- stearic acid
- mannitol.

Ikotab tablets do not contain sucrose, lactose, gluten, tartrazine or any other azo dyes.

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## Sponsor

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Aspen Pharma Pty Ltd  
34-36 Chandos Street  
St Leonards NSW 2065

Australian Register Numbers:

10 mg tablets: AUST R 218690

20 mg tablets: AUST R 218689

This leaflet was prepared in November 2014.