

APO-NICORANDIL

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 APO-NICORANDIL?

APO-NICORANDIL contains the active ingredient nicorandil. APO-NICORANDIL is used to treat chronic stable 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 APO-NICORANDIL?](#) in the full CMI.

2. What should I know before I use APO-NICORANDIL?

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 APO-NICORANDIL?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with APO-NICORANDIL 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 APO-NICORANDIL?

- Take APO-NICORANDIL exactly as your doctor has prescribed
- Your doctor will prescribe the correct dose for you depending on your condition and whether you are taking any other medicines

More instructions can be found in Section [4. How do I use APO-NICORANDIL?](#) in the full CMI.

5. What should I know while using APO-NICORANDIL?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using APO-NICORANDIL.• Tell your doctor if you are taking APO-NICORANDIL if you are about to have any blood tests or you are having surgery, or any anaesthetic or you are going into hospital
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine or lower the dosage without talking to your doctor• Do not give this medicine to anyone else, even if they have the same condition as you
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how APO-NICORANDIL affects you
Drinking alcohol	<ul style="list-style-type: none">• It is recommended to avoid alcohol while taking APO-NICORANDIL. The effects of alcohol could be made worse by taking APO-NICORANDIL
Looking after your medicine	<ul style="list-style-type: none">• Keep APO-NICORANDIL in a cool, dry place where the temperature stays below 25°C• Keep this medicine where children cannot reach it

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

6. Are there any side effects?

The most common side effect of APO-NICORANDIL is headache. **Tell your doctor immediately if you notice any of the following, these may be serious side effects and you may need urgent medical attention:** 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 and tongue ulcers or genital, anal or skin ulcers, dark bowel motions and/or bloody diarrhoea, inflammation of the bowel wall (fever, vomiting and stomach pain or discomfort), high potassium levels in the blood, nerve paralysis.

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.

APO-NICORANDIL

Active ingredient(s): *nicorandil*

Consumer Medicine Information (CMI)

This leaflet provides important information about using APO-NICORANDIL. **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 APO-NICORANDIL.**

Where to find information in this leaflet:

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

1. Why am I using APO-NICORANDIL?

APO-NICORANDIL contains the active ingredient nicorandil. Nicorandil 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, nicorandil has a "nitrate" property, which relaxes smooth muscle in the blood vessels, particularly in the veins.

APO-NICORANDIL is used to treat chronic stable 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 APO-NICORANDIL?

Warnings

Do not use APO-NICORANDIL if:

- You are allergic to nicorandil, nicotinic acid, nicotinamide, or any of the ingredients listed at the end of this leaflet.
- 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. rioriguat (Adempas®)

Check with your doctor if you:

- Have 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 or are planning to take any other medicines.
- You are planning to have surgery or an anaesthetic.
- You are currently receiving or are planning to receive dental treatment.

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

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

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 nicorandil 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

Nicorandil may also increase the effects of alcohol.

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

4. How do I use APO-NICORANDIL?

How much to take / use

- Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.
- The standard adult dose of nicorandil 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.

When to take / use APO-NICORANDIL

- APO-NICORANDIL should be taken in the morning and in the evening, either with or without food.
- Take nicorandil at about the same time each day.

How to take APO-NICORANDIL

- Swallow the tablet with a full glass of water.

If you forget to use APO-NICORANDIL

If you miss your dose at the usual time, 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 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 use too much APO-NICORANDIL

If you think that you have used too much APO-NICORANDIL, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), 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 APO-NICORANDIL?

Things you should do

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Things you should not do

- take more than the recommended dose unless your doctor tells you to.
- give this medicine to anyone else, even if they have the same condition as you.
- take your medicine to treat any other complaints unless your doctor tells you to.
- stop taking your medicine, 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.
- stop taking your tablets because you are feeling better, unless advised by your doctor or pharmacist.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how APO-NICORANDIL affects you.

APO-NICORANDIL may cause dizziness or lightheadedness in some people.

Drinking alcohol

Tell your doctor if you drink alcohol.

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

Looking after your medicine

- Store below 25°C
- Keep the tablets in their pack until it is time to take them. If you take your tablets out of the pack, they may not keep as well.

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.

Keep it where young children cannot reach it.

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.

Do not use this medicine after the expiry date.

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

Serious side effects

Serious side effects	What to do
<p>Allergy related:</p> <ul style="list-style-type: none"> cough, shortness of breath, wheezing, difficulty breathing or tightness in chest swelling of the face, lips, tongue, throat or other parts of the body rash, itching or hives on the skin fainting hay fever-like symptoms 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of</p>

<p>Cardiovascular</p> <ul style="list-style-type: none"> high blood pressure <p>Special senses</p> <ul style="list-style-type: none"> ringing or other persistent noise in the ears <p>Skin/ tissue</p> <ul style="list-style-type: none"> persistent mouth and tongue ulcers or genital, anal or skin ulcers <p>Gastrointestinal</p> <ul style="list-style-type: none"> dark bowel motions and/or bloody diarrhoea inflammation of the bowel wall (fever, vomiting and stomach pain or discomfort) <p>Metabolic</p> <ul style="list-style-type: none"> high potassium levels in the blood <p>Nervous system</p> <ul style="list-style-type: none"> nerve paralysis 	<p>these serious side effects.</p>
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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. 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 APO-NICORANDIL contains

Active ingredient (main ingredient)	10 mg or 20 mg of nicorandil
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> cetyl alcohol croscarmellose sodium povidone sodium stearyl fumarate mannitol
Potential allergens	n/a

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

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

What APO-NICORANDIL looks like

APO-NICORANDIL is available in two strengths:

- 10 mg tablet: white to off-white round tablets scored on one side and engraved with "10" on the other side. AUST R 277346
- 20 mg tablet: white to off-white round tablets scored on one side and engraved with "20" on the other side. AUST R 277343

Nicorandil 10 mg and 20 mg tablets are available in blister packs of 60 tablets in a carton.

Who distributes APO-NICORANDIL

Arrotex Pharmaceuticals Pty Ltd

15 – 17 Chapel St

Cremorne VIC 3121

Ph: 1800 195 055

This leaflet was prepared in November 2024.