

APO-Nicorandil Tablets

Contains the active ingredient nicorandil

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about nicorandil. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Nicorandil Tablets.

It contains the active ingredient nicorandil, which 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.

Nicorandil is used to treat chronic stable angina pectoris (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 this medicine has been prescribed for you. Your doctor may have prescribed this medicine for another reason.

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

There is no evidence that this medicine is addictive.

Use in children

There is not enough information to recommend this medicine for children or adolescents under 18 years of age.

Use in elderly

There is not enough information to recommend this medicine for children or adolescents under 18 years of age.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- 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®)
- You are hypersensitive to, or have had an allergic reaction 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.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- The expiry date (EXP) printed on the pack has passed.

If you take it after the expiry date has passed, it may not work as well.

- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. **You have allergies to:**
 - any other medicines
 - any of the ingredients listed at the end of this leaflet
 - any other substances, such as foods, preservatives or dyes.
2. **You are pregnant or intend to become pregnant.**

Your doctor will discuss the risks and benefits of taking it if you are pregnant.
3. **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 nicorandil. Your doctor will discuss the risks and benefits of taking it if you are breastfeeding.
4. **You have or have had any 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
5. You are planning to have surgery or an anaesthetic.
 6. You are currently receiving or are planning to receive dental treatment.
 7. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

If you have not told your doctor or pharmacist about any of the above, tell them before you take nicorandil.

Taking other medicines

Tell your doctor or pharmacist 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 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-inflammatory (NSAIDS) e.g. ibuprofen, diclofenac

Nicorandil may also increase the effects of alcohol.

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

If you are taking any of these you may need a different dose or you may need to take different medicines.

Your doctor or pharmacist will advise you.

How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

How much to take

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.

Your doctor may have prescribed a different dose.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

Follow the instructions they give you.

If you take the wrong dose, nicorandil may not work as well and your problem may not improve.

How to take it

Swallow the tablet with a full glass of water.

When to take it

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

Take nicorandil at about the same time each day.

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 for

Continue taking your medicine for as long as your doctor tells you.

Do not stop taking your medicine or change the dose of your medicine unless you are told to do so by your doctor.

Ask your doctor or pharmacist if you are not sure how long to take the medicine for.

Make sure you have enough to last over weekends and holidays.

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 to.

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

This may increase the chance of you experiencing side effects.

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 have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

If you take too much (overdose)

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

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

You may need urgent medical attention.

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

While you are taking this medicine

Things you must 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 pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Things you must not do

Do not:

- 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.
- 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.

Things to be careful of

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

Nicorandil may cause dizziness or lightheadedness 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.

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

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.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking nicorandil or if you have any questions or concerns.

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not.

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

You may not experience any of them.

Tell your doctor if you notice any of the following:

- headache
- 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
- skin abscess

The most common side effect of nicorandil is headache. This usually occurs in the first few

days after you start taking nicorandil and generally does not last long.

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

Tell your doctor immediately if you notice any of the following.

These may be serious side effects and you may need 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

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing

These are very serious side effects and you may need urgent medical attention or hospitalisation. Serious side effects are uncommon.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

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

Ask your doctor or pharmacist to answer any questions you may have.

Allergic reactions

If you think you are having an allergic reaction to nicorandil, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- 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.

Storage and disposal

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

Storage

Keep your medicine in the blister until it is time to take it.

If you take your medicine out of the blister it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C. Protect from light.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine 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 nicorandil, or the medicine has passed its expiry date, ask your pharmacist what to do with any tablets that are left over.

Return any unused medicine to your pharmacist.

Product description

What APO-Nicorandil Tablets looks like

Nicorandil tablets are 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.
- 20 mg tablet: white to off-white round tablets scored on one side and engraved with "20" on the other side.

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

Ingredients

Each tablet contains 10 mg or 20 mg of nicorandil as the active ingredient.

It also contains the following inactive ingredients:

- cetyl alcohol
- croscarmellose sodium
- povidone
- sodium stearyl fumarate
- mannitol

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

Australian Registration Numbers

APO-Nicorandil 10 mg Tablets (blister pack):
AUST R 277346.

APO-Nicorandil 20 mg Tablets (blister pack):
AUST R 277343.

Sponsor

Arrotex Pharmaceuticals
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