

APO-Perindopril Arginine

Contains the active ingredient perindopril arginine

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 perindopril arginine. 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 need to read it again.

What this medicine is used for

The name of your medicine is APO-Perindopril Arginine tablets.

It contains the active ingredient perindopril arginine.

Perindopril belongs to a group of medicines called angiotensin converting enzyme (ACE) inhibitors.

It is used to treat high blood pressure, heart failure or coronary artery disease.

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.

High blood pressure

Everyone has blood pressure. This pressure helps get your blood all around the body. Your blood pressure may be different at different times of the day, depending on how busy or worried you are. You have high blood pressure when your blood pressure stays higher than is needed, even when you are calm or relaxed. There are usually no symptoms of high blood pressure. The only way of knowing that you have it is to have your blood pressure checked on a regular basis. If high blood pressure is not treated it can lead to serious health problems. You may feel fine and have no symptoms, but eventually it can cause stroke, heart disease and kidney failure.

Perindopril arginine helps lower your blood pressure.

Heart failure

Heart failure means that the heart muscle cannot pump blood strongly enough to supply all the blood needed throughout the body. Heart failure is not the same as heart attack and does not mean that the heart stops working.

Some people develop heart failure after having had a heart attack.

However there are also other causes of heart failure.

Heart failure may start off with no symptoms, but as the condition progresses, you may feel short of breath or may get tired easily after light physical activity such as walking. You

may wake up short of breath at night. Fluid may collect in different parts of the body, often first noticed as swollen ankles and feet. In severe heart failure, symptoms may occur even at rest.

Perindopril arginine helps to treat heart failure. If you follow your doctor's advice, your ability to perform daily activities may improve. You may breathe more easily, feel less tired, and have less swelling.

Coronary artery disease

You may also have been prescribed perindopril arginine if you have coronary artery disease. Coronary artery disease is narrowing of the vessels carrying blood to the heart. In patients with coronary artery disease, perindopril arginine has been shown to reduce some of the risks, including heart attacks.

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.

Use in children

This medicine should not be used in children.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You have diabetes or kidney impairment and are taking aliskiren-containing products to treat high blood pressure.**
- **You are pregnant.**
- **you are breastfeeding or plan to breastfeed**
- **You undergo renal dialysis using polyacrylonitrile membranes.**
- **You have unilateral or bilateral renal artery stenosis**
(narrowing of the blood vessels to one or both kidneys).
- **You have experienced swelling of the face, tongue, lips or throat either spontaneously or in response to another medicine in the past.**

(This rare condition is known as angio-oedema)

- **You are hypersensitive to, or have had an allergic reaction to perindopril or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of

the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, 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.**
- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to take it

Tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - kidney disease
 - liver disease
 - high or low levels of potassium, or other problems with salt balance
 - diabetes

- heart disease
 - you are on a salt restricted diet or use salt substitutes which contain potassium
 - you are undergoing, or have had an allergic reaction during, previous low-density lipoprotein (LDL) apheresis, a technique where LDL is 'filtered' out of a patient's blood, using dextran sulphate
 - you have recently suffered from diarrhoea or vomiting.
 - you are undergoing desensitisation treatment, or have had an allergic reaction during previous desensitisation treatment (e.g. treatments using bee, wasp or ant venom).
3. You also take an 'angiotensin II receptor blocker' (also known as ARBs or sartans - for example valsartan, telmisartan, irbesartan), in particular if you have diabetes-related kidney problems,
 4. You are of African origin since you may have a higher risk of angioedema and this medicine is less effective in lowering your blood pressure.
 5. You plan to become pregnant. Do not take this medicine whilst pregnant.
 6. You plan to breastfeed. Do not take this medicine whilst breastfeeding.
 7. You are planning to have surgery or an anaesthetic.

8. You are currently receiving or are planning to receive dental treatment.
 9. 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.
- Taking other medicines

Some medicines may interact with perindopril. These include:

- Some antibiotic drugs
- Some anti-inflammatory drugs (including high dose aspirin, ibuprofen) for pain relief
- Medicines used to treat mood swings and some types of depression (lithium, tricyclic antidepressants, antipsychotics)
- Potassium-sparing diuretics, sources of potassium, like potassium tablet and salt substitutes containing potassium.
- Heparin (used to thin the blood)
- Immunosuppressants (medicines which reduce the activity of the body's natural defences)
- Some medications used to treat high blood pressure (including diuretics (sometimes called "fluid" or "water" tablets because they increase the amount of urine passed each day), a fast or irregular heartbeat, and other heart conditions)

- Vasodilators including nitrates
- Gold injections used for treating arthritis
- Medicines used to treat diabetes (tablets and insulin).

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

Other medicines not listed above may also interact with perindopril arginine.

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.

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

The dose of perindopril arginine you may need each day will be decided and adjusted by your doctor. This will normally be 2.5 mg, 5 mg or 10 mg once daily for high blood pressure and for people with coronary artery disease or 2.5 mg to 5 mg once daily for heart failure.

How to take it

Swallow your tablet(s) with a glass of water, before a meal.

When to take it

Take it at about the same time each day, preferably in the morning before a meal.

Taking your medicine at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take it for

Perindopril arginine helps control your condition but does not cure it.

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

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

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

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

This may increase the chance of unwanted side effects.

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)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.

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

If you take too much your blood pressure may fall (also known as hypotension), which can make you feel dizzy or faint.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you become pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breastfeed
- you are about to have any blood tests

- you are going to have surgery or an anaesthetic or are going into hospital.

Go to your doctor regularly for a check-up.

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

Things you must not do

Do not:

- Give this medicine to anyone else, even if they have the same condition as you.
- Use this medicine to treat other complaints unless your doctor tells you to.
- Stop taking this medicine or change the dosage, without checking with your doctor.

Things to be careful of

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

Dizziness or weakness due to low blood pressure may occur in certain patients. If you have any of these symptoms do not drive or operate machinery.

Possible side effects

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

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor or pharmacist if you notice any of the following:

- cough, often described as dry and irritating
- shortness of breath, discomfort on exertion
- headache, dizziness, vertigo, tinnitus (persistent noise in the ears)
- vision disturbances
- hypotension
- feeling tired or lethargic
- nausea vomiting, taste disturbances, indigestion, diarrhoea, constipation or abdominal pain
- muscle cramps
- rash, pruritus

- decreased blood sugar levels.

Tell your doctor as soon as possible if you notice any of the following.

These may be serious side effects and you may need medical attention:

- hypotension, flushing, impaired peripheral circulation, nose bleeds
- fainting
- eosinophilic pneumonia
- kidney problems (symptoms may include problems urinating)
- liver problems (symptoms may include yellowing of the skin and/or eyes)
- bleeding or bruising more easily than normal caused by a low blood platelet count, frequent infections such as fever, severe chills, sore throat or mouth ulcers caused by a lack of white blood cells, pancytopenia (a rare type of anaemia).

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects and you may need urgent medical attention or hospitalisation:

swelling of your lips, face, mouth, tongue or throat.

- changes in the rhythm or rate of the heartbeat, fast or irregular heartbeat,
- stroke, myocardial infarction, angina pectoris (a feeling of tightness, pressure or heaviness in the chest)
- purple spots with occasional blisters on the front of your arms and legs and/or around your neck and ears (a rare condition known as Stevens-Johnson Syndrome)
- difficulty breathing.

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

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place, away from light, where the temperature will stay below 25°C.

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 this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Perindopril Arginine looks like

2.5 mg tablets: White coloured, round shaped, biconvex, film coated tablets, with engraved "APO" on one side and "2.5" on the other side.

It is available in blister pack of 10, 30, 100 tablets and bottle pack of 30, 100 tablets

5 mg tablets: Light green coloured, capsule-shaped, biconvex, film coated tablets, with notch and engraved "APO" on one side and "P 5" on the other side.

It is available in blister pack of 10, 30, 100 tablets and bottle pack of 30, 100 tablets

10 mg tablets: Green coloured, round shaped, biconvex, film coated tablets, with engrave "APO" on one side and "P 10" on the other side.

It is available in blister pack of 10, 30, 100 tablets and bottle pack of 30, 100 tablets

Ingredients

Each tablet contains 2.5 mg, 5 mg or 10 mg of perindopril arginine as the active ingredient.

It also contains the following inactive ingredients:

- Isomalt
- Silica colloidal anhydrous
- Magnesium stearate
- Hypromellose
- Hydroxypropyl cellulose
- Macrogol 8000
- Titanium dioxide

5 mg and 10 mg tablets contain brilliant blue FCF and yellow iron oxide

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

Australian Registration Numbers

APO-Perindopril Arginine 2.5 mg tablet (blister pack): AUST R 184819.

APO- Perindopril Arginine 2.5 mg tablet (bottle): AUST R 184808.

APO-Perindopril Arginine 5 mg tablet (blister pack): AUST R 184814.

APO- Perindopril Arginine 5 mg tablet (bottle): AUST R 184806.

APO-Perindopril Arginine 10 mg tablet (blister pack): AUST R 184809.

APO- Perindopril Arginine 10 mg tablet (bottle): AUST R 184812.

Sponsor

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