

APO-Perindopril Arginine

Perindopril Arginine

Consumer Medicine Information

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

What is in this leaflet

This leaflet answers some common questions about this medicine. 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.

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 it 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.

Before you take this medicine

There are some people who should not take perindopril arginine. Please read the list below. If you think any of these situations apply to you or you have any questions, please consult your doctor.

When you must not take it

- **You are allergic to perindopril, any other ACE inhibitor or any of the ingredients listed at the end of this leaflet.**
- **You have experienced symptoms such as wheezing, swelling of the face, tongue, lips or throat, intense itching or severe skin rashes with previous ACE inhibitor treatment or if you or a member of your family have had these symptoms either spontaneously or, in response to another medicine in the past (a rare condition called angioedema).**
- **You are pregnant or trying to become pregnant.**
- **You are breastfeeding or plan to breastfeed.**
- **You undergo treatments where your blood is treated outside of the body (also known as extracorporeal treatments) that may increase your risk of allergic reactions, treatments such as:**
 - Renal dialysis or haemofiltration using polyacrylonitrile membranes.
 - Low-density lipoprotein (LDL) apheresis, a technique where LDL is 'filtered' out of the blood, using dextran sulfate.
- **You are treated with a blood pressure lowering medicine containing aliskiren and have diabetes or impaired kidney function.**
- **You have kidney problems where the blood supply to your kidney is reduced (renal artery stenosis).**
- **You are treated with sacubitril/ valsartan, a medicine used to treat long term heart failure (see sections 'Before you start to take it' and 'Taking Other Medicines').**
- **The packaging is damaged or shows sign of tampering.**
- **The expiry date (EXP) on the pack has passed.**

Before you start to take it

Tell your doctor immediately if:

- You are pregnant or become pregnant while taking perindopril arginine, as it may cause serious harm to your baby.

- You are undergoing desensitisation treatment, or have had an allergic reaction during previous desensitisation treatment (e.g. treatments using bee, wasp or ant venom).
- You are undergoing, or you are intending to undergo, treatments where your blood is treated outside the body (also known as extracorporeal treatments).
- You are to undergo anaesthesia and/or surgery.
- You have recently suffered from diarrhoea or vomiting or are dehydrated.
- You are on a salt restricted diet or use salt substitutes which contain potassium.
- You are taking lithium (used to treat mania or depression).
- You are taking any of the following medicines used to treat high blood pressure:
 - An 'angiotensin II receptor blocker' (also known as ARBs or sartans – e.g. valsartan, telmisartan, irbesartan), in particular if you have diabetes-related kidney problems.
 - Aliskiren.
 - Sacubitril (available as fixed-dose combinations with another medicine valsartan), used to treat long term heart failure.
- You have any other health problems, including:
 - Kidney disease, or if you are on renal dialysis.
 - Aortic stenosis (narrowing of the main blood vessel leading from the heart).
 - Liver disease.
 - High or low levels of potassium, or other problems with salt balance.
 - Diabetes.
 - Low blood pressure.
 - Heart disease, including hypertrophic cardiomyopathy (heart muscle disease).
 - Systemic lupus erythematosus or scleroderma (a disease affecting the skin, joints and kidneys).
 - Are of African origin, since you may have a higher risk of angioedema and this medicine is less effective in lowering your blood pressure.
 - Have abnormally increased levels of a hormone called aldosterone in your blood (primary aldosteronism).

If you think any of these situations apply to you, or you have any doubts, or questions about taking perindopril arginine, consult your doctor or pharmacist.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Taking perindopril arginine may change the effect of some medicines, and some medicines may affect how well perindopril arginine works. You may need different amounts of your medication or to take different medicines. The medicines that may interact with perindopril arginine include the following:

- Some medications used to treat high blood pressure (including angiotensin receptor blockers), aliskiren (see sections 'Before you take this medicine' - 'When you must not take this medicine' and 'Before you start to

take it' - 'Tell your doctor immediately if', diuretics (sometimes called 'fluid' or 'water' tablets because they increase the amount of urine passed each day).

- Some treatments where your blood is treated outside of the body, also known as extracorporeal treatments (see sections 'Before you take this medicine' - 'When you must not take this medicine' and 'Before you start to take it' - 'Tell your doctor immediately if').
- Some antibiotics and medicines used to treat infections.
- Some anti-inflammatory medicines (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, other medicines which can increase potassium in your body (such as heparin and cotrimoxazole also known as trimethoprim/sulfamethoxazole).
- Immunosuppressants (medicines which reduce the activity of the body's natural defences).
- Vasodilators including nitrates.
- Medicines used to treat diabetes (tablets and insulin).
- Medicines which may affect the blood cells, such as allopurinol, procainamide).
- Baclofen (a medicine used to treat muscle stiffness in diseases such as multiple sclerosis).
- Medicines used for the treatment of low blood pressure, shock or asthma (e.g. ephedrine, noradrenaline or adrenaline).
- Gold salts, especially with intravenous administration (used to treat symptoms of rheumatoid arthritis).
- Medicines which may increase the risk of angioedema (a severe allergic reaction) such as:
 - Mammalian target of rapamycin (mTOR) inhibitors used to avoid rejection of transplanted organs (e.g. temsirolimus, sirolimus, everolimus).
 - Sacubitril (available as fixed-dose combination with valsartan), used to treat long term heart failure treatments (see sections 'Before you take this medicine' - 'When you must not take this medicine' and 'Before you start to take it' - 'Tell your doctor immediately if').

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

For the Elderly or Children

Perindopril arginine can generally be used safely by the elderly. However, reduced kidney function is often found in the elderly and in this case, the starting dose should always be 2.5 mg.

Perindopril arginine is not recommended for children.

How to take this medicine

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the directions, ask your doctor or pharmacist for help.

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.

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

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

This medicine helps to control your condition but does not cure it. It is important to keep taking your medicine even if you feel well.

Continue taking your medicine until you finish the pack.

If you forget to take it

If it is almost time to take your next dose, skip the dose you missed and take your next dose when you are meant to.

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 the dose that you missed. This may increase the chance of you getting an unwanted side effect.

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.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much of this medicine. 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. If this happens, lying down with the legs elevated can help. Other effects like sickness, cramps, sleepiness, confusion, kidney problems, salt and water disturbances are possible. You may require urgent medical attention.

While you are using this medicine

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.

Make sure you drink enough water during exercise and hot weather especially if you sweat a lot. This will help you avoid dizziness

or light-headedness caused by a sudden drop in blood pressure.

Tell your doctor immediately if you have excessive vomiting or diarrhoea while taking this medicine.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant or start to breastfeed while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

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

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take this medicine to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

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

Things to be careful of

Be careful driving or operating machinery until you know how this medicine 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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking this medicine.

This medicine helps most people with high blood pressure, heart failure or coronary artery disease, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

Angioedema (a severe allergic reaction) has been reported in patients treated with ACE inhibitors, including perindopril arginine.

This may occur at any time during treatment. If you develop such symptoms described below, you should tell your doctor immediately or go to the Accident and Emergency Department at your nearest hospital. These side effects are extremely rare but can be serious:

- Swelling of your extremities (limbs, hands or feet), lips, face, mouth, tongue or throat.
- A fast and irregular heartbeat.
- 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 in breathing.

- Severe blisters, skin rash, itching, erythema multiforme or other allergic reactions.

Talk to your doctor or pharmacist if you notice any of the following side effects:

Common (may affect up to 1 in 10 people) side effects can include:

- Cough, often described as dry and irritating, shortness of breath, discomfort on exertion.
- Headache, dizziness, vertigo, pins and needles.
- Changes in the rhythm or rate of heartbeat, fast or irregular heartbeat.
- Feeling tired, lethargic or weak.
- Tinnitus (persistent noise in the ear), vision disturbances.
- Hypotension, flushing, impaired peripheral circulation, vasculitis, nose bleeds.
- Nausea, vomiting, taste disturbances, indigestion, diarrhoea, constipation, stomach pain or discomfort.
- Muscle cramps.
- Rash, pruritus (itching).

Uncommon (may affect up to 1 in 100 people) side effects can include:

- High levels in the blood of potassium, urea and/or creatine, low sodium levels in the blood.
- Mood disturbances, sleep disturbances (difficulty sleeping, abnormal dreams), feeling sleepy or drowsy, fainting.
- Difficulty in breathing or wheezing.
- Dry mouth.
- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.
- Excessive sweating.
- Increased sensitivity of the skin to sun, skin rash or inflammation of the skin often including blisters that weep and become crusted.
- Increase in some white blood cells.
- Erectile dysfunction.
- Fever or high temperature.
- Chest pain.
- Kidney problems.
- Decreased blood sugar levels.
- Aching muscles, muscle tenderness or weakness, not caused by exercise.
- Generally feeling unwell.
- Falls.

Rare (may affect up to 1 in 1,000 people) side effects can include:

- Elevation of bilirubin levels in the blood, increased liver enzymes.
- Worsening of psoriasis.

Very rare (may affect up to 1 in 10,000 people) side effects can include:

- Hepatitis.
- Inflammation of the pancreas (pancreatitis).
- Kidney disease.
- Eosinophilic pneumonia.
- Runny or blocked nose, sneezing, facial pressure or pain.
- Red, often itchy spots, similar to the rash of measles, which starts on the limbs and sometimes on the face and the rest of the body.
- Joint pain.
- Swelling of hands, ankles or feet.

- 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).
- Illnesses resulting from a lack of red blood cells.
- Stroke, myocardial infarction, angina pectoris (a feeling of tightness, pressure or heaviness in the chest).
- Changes in the rhythm or rate of the heartbeat.
- Confusion, depression or hallucinations.

Not known (frequency cannot be estimated from the data available):

- Discolouration, numbness and pain in fingers or toes (Raynaud's phenomenon).

Other:

Concentrated urine (dark in colour), feel or are sick, have muscle cramps, confusion and fits which may be due to inappropriate anti-diuretic hormone (ADH) secretion can occur with ACE inhibitors. If you have these symptoms contact your doctor as soon as possible.

Consult your doctor or pharmacist if you experience any of these or notice anything else that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience of them. Other uncommon side effects have been reported and you should ask your doctor or pharmacist if you want to know more.

Storage and Disposal

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

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

Do not store this 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 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

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

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 30 or 100 tablets and bottle pack of 30 or 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 30 or 100 tablets and bottle pack of 30 or 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 30 or 100 tablets and bottle pack of 30 or 100 tablets.

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.

Ingredients

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

This medicine also contains the following:

- Isomalt
- Colloidal anhydrous silica
- Magnesium stearate
- Hypromellose
- Hydroxypropyl cellulose
- Macrogol 8000
- Titanium dioxide

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

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

This medicine is supplied in Australia by:

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park NSW 2113
Tel: (02) 8877 8333
Web: www1.apotex.com/au

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