

APO-Perindopril/ Amlodipine 5/5, 5/10, 10/5 & 10/10 Tablets

Contains the active ingredient perindopril arginine and amlodipine (as besylate)

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 and amlodipine tablets. 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-Perindopril/Amlodipine 5/5, 5/10, 10/5 & 10/10 tablets. It contains the active ingredient perindopril arginine and amlodipine (as besylate).

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

Amlodipine belongs to a group of medicines called calcium channel blockers.

Calcium channel blockers do not change the amount of calcium in your blood or bones.

Perindopril/Amlodipine Tablets has been prescribed to you by your doctor to replace the separate tablets of perindopril and amlodipine you were taking.

One Perindopril/Amlodipine tablet replaces separate tablets of perindopril and amlodipine.

You have been prescribed Perindopril/Amlodipine tablets if you have high blood pressure, also known as hypertension.

Why Perindopril/Amlodipine is used for 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 stressed 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.

The active ingredients perindopril arginine and amlodipine help lower your blood pressure.

You may also have been prescribed this medicine if you have coronary heart disease.

Why Perindopril/Amlodipine is used for coronary heart disease

Coronary heart disease is narrowing of the vessels carrying blood to the heart.

In patients with coronary artery disease, perindopril and amlodipine 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.

How it works

Perindopril/Amlodipine tablets works by widening your blood vessels, which reduces pressure in the vessel, making it easier for your heart to pump blood around your body.

This helps increase the supply of oxygen to your heart, so that when you place extra demands on your heart, such as during exercise, your heart may cope better and you may not get short of breath as easily.

There is no evidence that this medicine is addictive.

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 are pregnant or trying to become pregnant.**

This medicine may affect your developing baby if you take it during pregnancy.

- **You are breastfeeding or plan to breastfeed.**

This medicine passes into breast milk and therefore there is a possibility that the breast fed baby may be affected.
- **You are hypersensitive to, or have had an allergic reaction to, perindopril or amlodipine or any of the ingredients listed at the end of this leaflet.**
- **You have had an allergic reaction to any other ACE inhibitors or calcium channel blockers.**

Symptoms of an allergic reaction may include: skin rash, itchiness, shortness of breath, swelling of the face, lips or tongue, muscle pain or tenderness or joint pain

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.

- **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 undergoing renal dialysis using polyacrylonitrile membranes**
- **You have renal artery stenosis (narrowing of the blood vessels to one or both kidneys)**
- **You have aortic stenosis (narrowing of the main blood vessel leaving from the heart)**
- **You have severe hypotension (low blood pressure)**
- **You have unstable angina**

Unstable angina is a pain or uncomfortable feeling in the chest that lasts longer than a few minutes or occurs with rest, and may not be relieved with medication
- **You have had cardiogenic shock which is a sudden and severe drop in blood pressure and blood flow through the body because the heart is not pumping normally**
- **You have had heart failure during the first 28 days after a heart attack (Heart failure means that the heart muscle cannot pump blood strongly enough to supply all the blood needed throughout the body. It does not mean that the heart stops working)**

- 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.

For older people and patients with renal impairment

This medicine can generally be used safely by elderly people.

Reduced kidney function is often found in elderly people and in this case, the starting dose should always be 2.5mg of perindopril arginine and 2.5mg of amlodipine taken as separate tablets.

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 other substances, such as foods, preservatives or dyes.
2. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant as it may cause serious harm to your baby.
3. You have or have had any medical conditions, especially the following:
 - 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 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 are to undergo anaesthesia and/or surgery
 - you have recently suffered from diarrhoea or vomiting

- you are on a salt restricted diet or use salt substitutes which contain potassium
 - you are treated with immunosuppressant therapy or allopurinol or procainamide
4. You have any other health problems, including:
- kidney disease or if you undergo renal dialysis
 - liver disease
 - high or low levels of potassium, or other problems with salt balance
 - diabetes
 - heart disease
 - systemic lupus erythematosus or scleroderma (a disease affecting the skin, joints and kidneys)
5. 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.

Some medicines may interact with perindopril and/or amlodipine. These include:

- tetracycline antibiotic drugs such as erythromycin and rifampicin
- some anti-inflammatory drugs (including high dose aspirin, ibuprofen to relieve pain swelling and other symptoms of inflammation, including arthritis, and gold injections to treat rheumatoid arthritis)
- 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 blood)
- some medications used to treat high blood pressure (including angiotensin receptor blocker, beta-blockers, alpha-blockers or diuretics (sometimes called "fluid" or "water" tablets because

they increase the amount of urine passed each day)

- vasodilators including nitrates
- medicines used to treat diabetes (tablets and insulin).
- muscle relaxants such as baclofen and dantrolene
- medicines used to treat epilepsy such as carbamazepine, phenobarbital, phenytoin or primidone
- medicines which lower your immune system, such as corticosteroids, cyclosporine or medicines used to treat cancer (including radiation therapy)
- some medicines used to treat some fungal infections
- medicines which may affect the blood cells, such as allopurinol, procainamide

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 and/or amlodipine.

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. The usual dose is one tablet once daily.

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.

How to take it

Swallow your tablet with a glass of water.

When to take it

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

This medicine should be taken in the morning before a meal.

How long to take it for

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 you experiencing 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.

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 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.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. 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 their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.
- Stop taking your tablets because you are feeling better, unless advised by your doctor.

Things that may help your condition

Some self-help measures suggested below may help your condition. Talk to your doctor or pharmacist about these measures and for more information.

- Alcohol - your doctor may advise you to limit your alcohol intake

- Diet - eat a healthy low-fat diet which includes plenty of fresh vegetables, fruit, bread, cereals and fish. Also eat less fat and sugar.
- Exercise - regular exercise helps to reduce blood pressure and helps get the heart fitter, but it is important not to overdo it.

Walking is good exercise, but try to find a route that is reasonably flat. Before starting any exercise, ask your doctor about the best kind of program for you.
- Salt - your doctor may advise you to watch the amount of salt in your diet. To reduce your salt intake you should avoid using salt in cooking or at the table.
- Smoking - your doctor may advise you to stop or at least cut down smoking.
- Weight - your doctor may suggest losing some weight to help lower your blood pressure and help lessen the amount of work your heart has to do. Some people may need a dietician's help to lose weight.

Things to be careful of

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

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking Perindopril/Amlodipine Tablets 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 if you notice any of the following and they worry you:

- feeling light-headed, dizzy

- vertigo
- headache
- dry cough
- feeling tired or lethargic (fatigue)
- feeling sleepy
- ringing or buzzing in the ears (tinnitus)
- feeling sick (nausea) or vomiting
- diarrhoea
- constipation
- an uncomfortable feeling in the stomach or belching after eating, indigestion
- stomach pain
- flushed skin
- taste disturbances or loss of taste
- vision disturbances
- muscle cramps
- coldness, tingling or numbness of the hands or feet, pins and needles
- fast or irregular heart beats, also called palpitations
- shortness of breath
- difficulty in breathing or chest tightness
- rash, itching, eczema,
- swelling of hands, ankles or feet
- swelling of the joints
- nose-bleeds
- erectile dysfunction
- increased blood sugar
- exceptional cases of extrapyramidal syndrome (a type of movement disorder)

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:

- 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)

- a fast and irregular heart beat
- severe blisters, skin rash, itching, reddening, peeling and swelling or other allergic reactions
- pancreatitis
- hepatitis
- acute renal failure
- severe blood disorders
- fainting

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

Allergic reactions

If you think you are having an allergic reaction to perindopril and/or amlodipine, 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 or difficulty breathing
- 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

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 where the temperature will stay below 25°C.

Keep the container tightly closed and protect from moisture.

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/Amlodipine 5/5, 5/10, 10/5 & 10/10 Tablets looks like

5 mg/5 mg Tablet

White to off-white coloured, oval-shaped biconvex tablets engraved with "APO" on one side and "5/5" on the other side.

5 mg/10 mg Tablet

White to off-white coloured, square-shaped biconvex tablets engraved with "APO" on one side and "5/10" on the other side.

10 mg/5 mg Tablet

White to off-white coloured, triangular-shaped biconvex tablets engraved with "APO" on one side and "10/5" on the other side.

10 mg/10 mg Tablet

White to off-white coloured, round-shaped biconvex tablets engraved with "APO" on one side and "10/10" on the other side.

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each tablet contains perindopril arginine and amlodipine (as besylate)

respectively: 5 mg/5 mg, 5 mg/10 mg, 10 mg/5 mg & 10 mg/10 mg as the active ingredients.

It also contains the following inactive ingredients:

- microcrystalline cellulose,
- croscarmellose sodium,
- colloidal silica anhydrous,
- magnesium stearate.

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

Australian Registration Numbers

APO-Perindopril/Amlodipine 5/5 Tablet

Bottle (round HDPE bottle with child-resistant cap and desiccant) of 30 tablets: AUST R 224306.

Blister (Aluminium/Aluminium silver foil) of 30 tablets: AUST R 224333.

APO-Perindopril/Amlodipine 5/10 Tablet

Bottle (round HDPE bottle with child-resistant cap and desiccant) of 30 tablets: AUST R 224292.

Blister (Aluminium/Aluminium silver foil) of 30 tablets: AUST R 224325.

APO-Perindopril/Amlodipine 10/5 Tablet

Bottle (round HDPE bottle with child-resistant cap and desiccant) of 30 tablets: AUST R 224316.

Blister (Aluminium/Aluminium silver foil) of 30 tablets: AUST R 224309.

APO-Perindopril/Amlodipine 10/10 Tablet

Bottle (round HDPE bottle with child-resistant cap and desiccant) of 30 tablets: AUST R 224300.

Blister (Aluminium/Aluminium silver foil) of 30 tablets: AUST R 224312.

Sponsor

Apotex Pty. Ltd.

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