

# APO-Perindopril Tablets

Contains the active ingredient perindopril erbumine

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## Consumer Medicine Information

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

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### What is in this leaflet

#### Read this leaflet carefully before taking your medicine.

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

#### 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](http://www.apotex.com.au).

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.

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

If you have any concerns about taking this medicine, ask your doctor, pharmacist, or nurse. Keep this leaflet with your medicine.

You may want to read it again.

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### What this medicine is used for

The name of your medicine is APO-Perindopril tablets.

It contains the active ingredient perindopril erbumine.

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 to circulate 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 (also known as hypertension) when your blood pressure stays higher than is needed, even when you are calm and 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 helps to lower your blood pressure.

#### Heart failure

Heart failure means that the heart muscle is not pumping blood strongly enough to circulate blood around the body properly. Heart failure is not the same as a heart attack and does not mean that the heart stops working. Some people may develop heart failure after having a heart attack, but there are a number of 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 get tired easily after light physical activity such as walking. Fluid may accumulate in different parts of the body, often first noticed as swollen ankles and feet. You may also wake up short of breath at night. In severe heart failure, symptoms like breathlessness may occur even at rest.

Perindopril 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

Coronary artery disease is narrowing of the vessels carrying blood to the

heart. In patients with coronary artery disease, perindopril has been shown to reduce some of the risks, including heart attacks.

There is no evidence that this medicine is addictive.

### **Use in children**

This medicine should not be used in children.

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## **Before you take this medicine**

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### **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.**  
Perindopril may affect your developing baby if you take it during pregnancy.
- **You are breastfeeding.**  
It is not known if perindopril passes into human breast milk.
- **You are undergoing 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 sulphate.
- **You are treated with a blood pressure lowering medicine containing aliskiren and have diabetes or impaired kidney function.**
- **You are treated with sacubitril/valsartan a medicine used to treat long-term heart failure (see also 'Tell your doctor' and**

### **'some medicines that may interact with perindopril'**

- **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 suddenly or in response to another ACE inhibitor medicine**  
(a rare allergic condition 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, 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 are intolerant or allergic to lactose.**  
This medicine contains lactose.
- **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:

- narrowing of the main blood vessel leading from the heart (aortic stenosis)
- kidney disease
- liver disease
- heart disease (including hypertrophic cardiomyopathy)
- low blood pressure
- diabetes
- systemic lupus erythematosus or scleroderma (a disease affecting the skin, joints and kidneys)
- have abnormally increased levels of a hormone called aldosterone in your blood (primary aldosteronism).
- high or low levels of potassium, sodium or other problems with salt balance
- 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 are undergoing, or you are intending to undergo, treatments where your blood is treated outside of the body (also known as extracorporeal treatments).
- you have recently suffered from diarrhoea or vomiting or are dehydrated.
- You have an intolerance to some sugars as this medicine contains lactose.
- 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 taking lithium (used to treat mania or depression).
5. 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.
6. You plan to become pregnant. Do not take this medicine whilst pregnant.
7. You plan to breastfeed. Do not take this medicine whilst breastfeeding.
8. You are planning to have surgery or an anaesthetic.
9. You are currently receiving or are planning to receive dental treatment.
10. 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 think any of these situations apply to you, or you have any doubts or questions about taking this medicine consult your doctor or pharmacist.**

Some medicines may interact with perindopril. These include:

- some antibiotic drugs
- some medicines used to treat high blood pressure (including angiotensin receptor blockers), aliskiren (see also ‘when you must not take this medicine’ and ‘tell your doctor if:’)
- 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 tablets and salt substitutes containing potassium, other drugs which can increase potassium in your body (such as heparin and cotrimoxazole also

known as trimethoprim/  
sulfamethoxazole)

- 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), a fast or irregular heartbeat and other heart conditions
- vasodilators including nitrates
- medicines used to treat diabetes (tablets and insulin)
- medicines that may affect the blood cells, such as allopurinol, procainamide
- baclofen (a medicine used to treat muscle stiffness in disease such as multiple sclerosis)
- medicines used for the treatment of low blood pressure, shock, or asthma (e.g. ephedrine, noradrenaline, or adrenaline (epinephrine))
- gold injections used for treating rheumatoid arthritis.
- Some treatments where your blood is treated outside of the body, also known as extracorporeal treatments.
- 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

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.

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## How to take this medicine

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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 usual starting dose for high blood pressure or coronary artery disease is 4 mg once daily, which may be increased by your doctor up to 8mg once daily

The usual starting dose for heart failure is 2 mg once daily, which may be increased by your doctor up to 4mg once daily.

Elderly people can generally use perindopril safely. However, some older people have reduced kidney function, in which case the starting dose of perindopril should be 2 mg once daily. A less frequent dose may be prescribed with serious kidney 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**

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

Perindopril can help control your condition, but cannot cure it.

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.**

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

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## **While you are taking this medicine**

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### ***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 breastfeed
- 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

### ***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.

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## **Possible side effects**

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Tell your doctor as soon as possible if you do not feel well while you are taking perindopril 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:**

- Hypotension
- cough, often described as dry and irritating
- shortness of breath, discomfort on exertion
- headache, dizziness, vertigo, pins and needles
- changes in rhythm or rate of heart beat, fast or irregular heart beat
- feeling tired or lethargic
- tinnitus (persistent noise in the ears)
- vision disturbances
- nausea, vomiting, taste disturbances, indigestion, diarrhoea, constipation or abdominal pain
- muscle cramps
- rash, pruritus (itching)
- 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
- high levels in the blood of potassium, urea and/or creatine, low sodium levels in the blood
- mood disturbance, sleep disturbance (difficulty sleeping, abnormal dreams), feeling sleepy or drowsy, fainting
- dry mouth
- excessive sweating
- increased sensitivity of the skin to sun, skin rash or inflammation of the skin often including blisters that weep and become crusted
- erectile dysfunction
- excessive sweating
- chest pain
- decreased blood sugar levels
- generally feeling unwell
- falls

- 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 in the face, lips, 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 in breathing.

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

### **Allergic reactions**

**If you think you are having an allergic reaction to perindopril, 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.

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## **Storage and disposal**

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### **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

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.

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## **Product Description**

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### **What APO-Perindopril looks like**

APO-Perindopril 2 mg tablets are white, round, biconvex tablets, engraved "APO" on one side and "PE2" on the reverse.

Blister packs of 30 tablets.

APO-Perindopril 4 mg tablets are white, capsule shaped, biconvex tablets, scored and engraved "PE" bisect "4" on one side, and "APO" on the reverse.

Blister packs of 30 tablets.

APO-Perindopril 8 mg tablets are white, capsule shaped, biconvex tablets, scored and engraved "PE" bisect "8" on one side, and "APO" on the reverse.

Blister packs of 30 tablets.

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

### **Ingredients**

Each tablet contains 2 mg, 4 mg or 8 mg perindopril erbumine as the active ingredient.

It also contains the following inactive ingredients:

- lactose anhydrous
- magnesium stearate.

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

### **Australian Registration Numbers**

**APO-Perindopril 2 mg tablets**

AUST R 151911

**APO-Perindopril 4 mg tablets**

AUST R 151912

**APO-Perindopril 8 mg tablets**

AUST R 151913

### **Sponsor**

Apotex Pty Ltd

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