

# APO-Enalapril

*Contains the active ingredient enalapril (as enalapril maleate)*

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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

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.

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### What this medicine is used for

Enalapril is used to treat:

- heart failure
- high blood pressure (also known as hypertension)

Enalapril belongs to a group of medicines called Angiotensin Converting Enzyme (ACE) inhibitors.

One of the ways enalapril helps lower blood pressure and treat heart failure is that it widens blood vessels.

This means that blood is able to pass through them more easily and the heart doesn't have to pump as hard to move blood around the body. This also means that when you place extra demands on your heart, such as during exercise, the heart may cope

better so you may not get short of breath as easily.

#### **Hypertension**

Everyone has blood pressure. This pressure helps get your blood all around your body. Your blood pressure may be different at different times of the day, depending on how busy or worried you are. You have hypertension (high blood pressure) when your blood pressure stays higher than is needed, even when you are calm and relaxed.

There are usually no symptoms of hypertension. The only way of knowing that you have hypertension 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 hypertension can cause stroke, heart disease and kidney failure.

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

Fluid may also collect in different parts of the body, often first noticed as swollen ankles and feet.

Enalapril helps to treat heart failure, whether you have symptoms or not.

It does this by helping to stop the heart muscle from getting weaker. It may also slow down the development of symptoms, such as shortness of breath, tiredness after light physical activity, or swelling of the ankles and feet. By slowing down the progression of heart failure, enalapril reduces the chance of having a heart attack, or needing to go to hospital as a result of heart failure.

**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.

This medicine should not be used in children.

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### Before you take this medicine

#### *When you must not take it*

**Do not take this medicine if you have an allergy to:**

- any medicine containing enalapril or any other ACE inhibitor
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing

- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

**Do not take this medicine if you have a history of swelling of the face, lips, tongue, throat, hands or feet, for no apparent reason.**

**Do not take this medicine if you have diabetes while also taking aliskiren for blood pressure control.**

**Do not take this medicine if you are taking a medicine containing a neprilysin inhibitor (e.g. sacubitril).**

Do not take enalapril for at least 36 hours before or after you take any medicine containing a neprilysin inhibitor (e.g. sacubitril) or combinations including these medicines (e.g. sacubitril/valsartan).

**Do not take this medicine if you are pregnant.**

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

**Do not breastfeed if you are taking this medicine.**

Enalapril may pass into breast milk and there is a possibility that your baby may be affected.

**If you are not sure whether you should start taking this medicine, talk to your doctor.**

### *Before you start to take it*

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you have or have had any of the following medical conditions:**

- kidney disease, or are undergoing dialysis
- diabetes
- heart problems

**Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.**

This medicine should not be used during pregnancy or while breastfeeding.

**Tell your doctor if you have recently suffered from excessive vomiting or diarrhoea.**

**Tell your doctor if you are following a very low salt diet.**

**Tell your doctor if you are taking potassium supplements, potassium-sparing agents, potassium-containing salt substitutes or other drugs that may increase serum potassium (e.g. trimethoprim-containing products).**

**Tell your doctor if you suffer from low blood pressure.**

You may notice this as faintness or dizziness, especially when standing.

**Tell your doctor if you are planning to have surgery and anaesthesia (even at the dentist's office).**

You may experience a sudden fall in blood pressure associated with anaesthesia.

**If you have not told your doctor about any of the above, tell them before you start taking this medicine.**

### *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.**

Some medicines may interact with enalapril. These include:

- other blood pressure medicines (some medications are not recommended while taking enalapril – speak to your doctor to confirm)
- diuretic tablets – also called fluid or water tablets
- lithium, used to treat mood swings and some types of depression
- potassium tablets
- potassium-containing salt substitutes
- potassium-sparing agents (e.g. spironolactone, eplerenone, triamterene or amiloride)
- other drugs that may increase serum potassium levels (e.g. trimethoprim-containing products)

- non-steroidal anti-inflammatory medicines (NSAIDs or COX-2 inhibitors), used to relieve pain, swelling and other symptoms of inflammation
- arthritis medicines, including gold therapy
- insulin or oral anti-diabetic medicines – you should be closely monitored for low blood glucose levels, especially during the first month of treatment with enalapril
- mTOR inhibitors (e.g. temsirolimus, sirolimus or everolimus)
- a medicine containing a neprilysin inhibitor (e.g. sacubitril)

These medicines may be affected by enalapril or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Other medicines not listed above may also interact with enalapril.

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

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## How to take this medicine

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**Follow carefully all directions given to you by your doctor.**

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.

If you are over the age of 65 years, your doctor may start you on a lower dosage.

**For high blood pressure:**

For most patients, the usual starting

dose is 5 mg taken once a day. Some patients may need a lower starting dose. The dose may need to be increased depending on your blood pressure. Most patients take between 10 to 40 mg each day.

#### **For heart failure:**

The usual starting dose is 2.5 mg taken once a day. Depending on your response, this dose may need to be increased up to 20 mg each day. This dose may be taken once a day or divided into two doses per day.

#### *How to take it*

**Swallow the tablets with a glass of water.**

#### *When to take it*

**Take your medicine at about the same time each day.**

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

It does not matter if you take this medicine before or after food.

#### *How long to take it for*

**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 every day, even if you feel well.

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 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 enalapril, you will may feel light-headed or dizzy, or you may faint.

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

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#### *Things you must do*

**Tell your doctor if you have had excessive vomiting or diarrhoea, or if you experience any of the following symptoms:**

- light-headedness or dizziness
- dry mouth or thirst
- weakness, tiredness or drowsiness
- muscle pain or cramps
- a fast heart beat
- passing less urine than normal

If you experience these symptoms, you may be dehydrated because you are losing too much water. This is more likely to occur when you begin to take enalapril or if your dose is increased.

Make sure you drink enough water during exercise and hot weather when you are taking enalapril, especially if you sweat a lot.

If you do not drink enough water while taking enalapril, your blood pressure may drop suddenly, and you may dehydrate. If you experience any of the above symptoms, tell your doctor.

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are 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, such as checking your blood pressure, 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 lower the dosage without checking with your doctor.**

#### *Things to be careful of*

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

Enalapril may cause dizziness or light-headedness in some people, especially after the first dose or if the dose is increased. Make sure you know how you react to enalapril before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed.

If you drink alcohol, the dizziness or light-headedness may be worse.

### ***Things that would be helpful for your blood pressure or heart failure***

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 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 the heart get fitter, but it is important not to overdo it. Walking is a good exercise but try to find a route that is fairly flat. Before starting any exercise, ask your doctor about the best kind of programme 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 smoking or at least cut down
- Weight – your doctor may suggest losing some weight to help lower your blood pressure and help lessen the amount of work your heart must do. Some people may need a dietitian's help to lose weight

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## **Side effects**

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

All medicines can have side effects. Sometimes they are serious but most of the time they are not. You may need medical attention if you get some of the side effects.

If you are over 65 years of age you may have an increased chance of getting 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.**

**Tell your doctor if you notice any of the following:**

- light-headedness or dizziness because blood pressure is too low
- headache
- fatigue
- dry cough
- mild stomach upsets such as feeling sick, diarrhoea, or stomach pains
- muscle cramps

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

- changes in the way your heart beats, e.g. if you notice it beating faster
- fainting
- yellowing of the skin and eyes (also called jaundice)
- itchy skin rash or other skin problems
- signs of worrying or frequent infections such as fever, severe chills, sore throat or mouth ulcers
- passing less urine than is normal for you
- signs of dehydration such as nausea, vomiting, muscle cramps, headache, drowsiness and tiredness – if untreated, mental confusion and fits may develop. Your doctor may need to monitor your blood sodium levels.

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

Mostly, these side effects are rare.

**If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- pinkish, itchy swellings on the skin, also called hives or nettle rash

- flu-like symptoms, followed by a painful red or purplish rash on skin and mucous membranes (mouth/nose, eyelids, genitals, internal organs) that spreads and blisters
- chest pain or angina
- wheeziness due to tightness in the chest
- collapsing, numbness or weakness of arms or legs
- symptoms of an allergic reaction including 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

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

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

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

Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

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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 the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

### *Sponsor*

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This leaflet was last updated in November 2019.

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## Product description

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### *What APO-Enalapril Tablets looks like*

#### **5 mg tablets**

White to off white, round, flat-face bevelled edge tablets break line on one side and "5" debossed on the other side. AUST R 196472.

#### **10 mg tablets**

White to off white, round, flat-face bevelled edge tablets with break line on one side and "10" debossed on the other side. AUST R 196466.

#### **20 mg tablets**

White to off white, round, flat-face bevelled edge tablets with break line one side and "20" debossed on the other side. AUST R 196504.

Available in blister packs of 30.

### *Ingredients*

Each tablet contains 5 mg, 10 mg or 20 mg of enalapril maleate as the active ingredient.

It also contains the following inactive ingredients:

- maleic acid
- lactose monohydrate
- hypromellose
- croscarmellose sodium
- sodium stearyl fumarate

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