

APO-Enalapril

Contains the active ingredient enalapril (as enalapril maleate)

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 enalapril. 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-Enalapril tablets. It contains the active ingredient enalapril maleate.

It is used to treat heart failure.

It lowers high blood pressure, which doctors call hypertension.

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. It helps to 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. 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 activity such as walking. Some patients 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.

Enalapril helps to treat heart failure, whether you have symptoms or not. In many patients with heart failure who have symptoms, it may slow the progression of heart failure and reduce the need to go to hospital as a result of heart failure. It may help some of these patients live longer.

In many patients with heart failure who have no symptoms, enalapril may help 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. These patients may be less likely to have hospital stays due to heart failure.

By taking this medicine, heart failure patients may have less chance of having a heart attack.

When used to treat heart failure, enalapril is almost always used with other medicines called diuretics or fluid tablets. These medicines help the kidney get rid of excess fluid from the body.

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

One of the ways this medicine 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.

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

Your doctor may prescribe this medicine for another reason. Ask your doctor if you have any questions about why this medicine has been prescribed for you.

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 have taken any other 'ACE inhibitor' medicines for high blood pressure or heart failure before, which caused your face, lips, tongue, throat, hands or feet to swell up, or made it hard for you to breathe.**

If you have had an allergic reaction to an ACE inhibitor before, you may be allergic to enalapril.

- **You have an allergy to enalapril, or any of the ingredients listed at the end of this leaflet.**

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 a history of swelling of the face, lips, tongue, throat, hands or feet, for no apparent reason.**

- **You have diabetes while also taking aliskiren (Rasilez) for blood pressure control.**
- **You are pregnant.**

Do not take enalapril if you are pregnant or breastfeeding. Your baby may absorb this medicine in the womb or from breast milk and therefore there is a possibility of harm to the baby.

- 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.

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

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 have or have had any medical conditions, especially the following:

- kidney disease, or are undergoing dialysis
- diabetes

- heart problems
- 3. You are or intend to become pregnant or intend to breastfeed.**

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

- 4. You have recently suffered from excessive vomiting or diarrhoea.**

- 5. You are following a very low salt diet.**

- 6. You suffer from low blood pressure**

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

- 7. You are planning to have surgery and anaesthesia (even at the dentist office)**

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

Taking other medicines

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, a medicine used to treat mood swings and some types of depression
- potassium tablets
- potassium-containing salt substitutes
- potassium-sparing agents (e.g. spironolactone, eplerenone, triamterene, amiloride), non-steroidal anti-inflammatory medicines (NSAIDs or "Coxibs"/COX-2 inhibitors), used to relieve pain, swelling and other symptoms of inflammation
- arthritis medicines including gold therapy
- insulin or oral antidiabetic 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, everolimus).

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 enalapril.

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.

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 2.5mg 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 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.

It does not matter if you take it before, with 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 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.

If you are not sure whether to skip the dose, talk to your doctor.

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.

If you take too many tablets, you will probably feel light-headed or dizzy, or you may faint.

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

If you become pregnant while taking this medicine, tell your doctor immediately.

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

- light-headed or dizzy
- dry mouth or thirst
- weakness, tiredness or drowsiness
- muscle pain or cramps
- 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.

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are breastfeeding or are planning to breast-feed
- you are going to have surgery or an anaesthetic or are going into hospital.

Having a general anaesthetic while taking this medicine may cause your blood pressure to drop suddenly.

- you are about to have any blood tests

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 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, 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 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 has to do. Some people may need a dietician's help to lose weight.

Possible side effects

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

- 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.

These may be serious side effects and you may need medical attention. Mostly, these side effects are rare:

- changes in the way your heart beats, for example, 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.

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. These side effects are usually very rare:

- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- swelling of the hands, feet, or ankles
- pinkish, itchy swellings on the skin, also called hives or nettlerash
- 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, angina

- wheeziness due to tightness in the chest
- collapse, numbness or weakness of arms or legs

Other side effects not listed above may occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them

Allergic reactions

If you think you are having an allergic reaction to enalapril, 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.

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-Enalapril Tablets looks like

5 mg tablets:

White to off white, round, flat-face beveled edge tablets breakline on one side and "5" debossed on the other side.

10 mg tablets:

White to off white, round, flat-face beveled edge tablets with breakline on one side and "10" debossed on the other side.

20 mg tablets:

White to off white, round, flat-face beveled edge tablets with breakline one side and "20" debossed on the other side.

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.

Australian Registration Numbers

APO-Enalapril 5mg Tablets (PVC/PVDC/Al): AUST R
196472.

APO-Enalapril 10mg Tablets (PVC/PVDC/Al): AUST R
196466.

APO-Enalapril 20mg Tablets (PVC/PVDC/Al): AUST R
196504.

Sponsor

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