

ENALAPRIL ACTAVIS

Enalapril maleate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ENALAPRIL ACTAVIS. 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 ENALAPRIL ACTAVIS 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 ENALAPRIL ACTAVIS is used for

ENALAPRIL ACTAVIS lowers high blood pressure, which doctors call hypertension. It is also used to treat heart failure.

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. ENALAPRIL ACTAVIS 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 ACTAVIS helps to treat heart failure, whether you have symptoms or not. In many patients with heart failure who have symptoms, ENALAPRIL ACTAVIS may slow the progression of heart failure and reduce the need to go to hospital as a result of heart failure.

ENALAPRIL ACTAVIS may help some of these patients live longer.

In many patients with heart failure who have no symptoms, ENALAPRIL ACTAVIS may help to stop the heart muscle from getting weaker. ENALAPRIL ACTAVIS 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 ENALAPRIL ACTAVIS, heart failure patients may have less chance of having a heart attack.

When used to treat heart failure, ENALAPRIL ACTAVIS 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.

How ENALAPRIL ACTAVIS works

One of the ways ENALAPRIL ACTAVIS 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 ENALAPRIL ACTAVIS for another reason. Ask your doctor if you have any questions about why ENALAPRIL ACTAVIS has been prescribed for you.

ENALAPRIL ACTAVIS is not addictive

Before you take ENALAPRIL ACTAVIS

When you must not take it

Do not take ENALAPRIL ACTAVIS 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 ACTAVIS.

- **you have an allergy to ENALAPRIL ACTAVIS, Amprace® or other brands of enalapril maleate, or any of the ingredients listed at the end of this leaflet**

Symptoms of an allergic reaction to ENALAPRIL ACTAVIS or other brands of enalapril maleate may include skin rash, itchiness, shortness of breath, swelling of the face, lips or tongue, muscle pain or tenderness or joint pain.

- **you have a history of swelling of the face, lips, tongue, throat, hands or feet, for no apparent reason.**
- **you have diabetes and are taking a medicine called aliskiren to reduce blood pressure.**

Do not take ENALAPRIL ACTAVIS if you are pregnant or breast-feeding.

Your baby may absorb this medicine in the womb or from breast milk and therefore there is a possibility of harm to the baby.

Do not take ENALAPRIL ACTAVIS if:

- **the packaging is torn or shows signs of tampering**
- **the expiry date on the pack has passed.**

If you take this medicine after the expiry date has passed, it may not work.

If you are not sure whether you should start taking ENALAPRIL ACTAVIS, talk to your doctor.

Before you start to take it

Tell your doctor if:

1. **you are or intend to become pregnant or intend to breastfeed**
ENALAPRIL ACTAVIS should not be used during pregnancy or while breastfeeding.
2. **you have any medical conditions, especially the following:**
 - kidney disease, or are undergoing dialysis
 - diabetes
 - heart problems
3. **you have recently suffered from excessive vomiting or diarrhoea**
4. **you are following a very low salt diet**
5. **you have had an allergy to any other medicines or any other substances, such as foods, preservatives or dyes.**
6. **if you suffer from low blood pressure (you may notice this as faintness or dizziness, especially when standing).**
7. **surgery and anaesthesia (even at the dentist office) are scheduled, as there may be 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 take any ENALAPRIL ACTAVIS.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines and ENALAPRIL ACTAVIS may interfere with each other.

These include:

- **other blood pressure medicines**
- 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 ACTAVIS.

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

Your doctor or pharmacist has more information on medicines to avoid while taking ENALAPRIL ACTAVIS.

How to take ENALAPRIL ACTAVIS

How much to take

Your doctor will tell you how many tablets you need to take each day. This depends on your condition and whether you are taking other medicines. Take ENALAPRIL ACTAVIS only when prescribed by your doctor.

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.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How to take it

Take your ENALAPRIL ACTAVIS at about the same time each day.

Taking your tablet(s) at the same time each day will have the best effect. It will also help you remember when to take the tablets.

It does not matter if you take ENALAPRIL ACTAVIS before or after food.

Swallow ENALAPRIL ACTAVIS with a glass of water.

How long to take it

ENALAPRIL ACTAVIS helps control your high blood pressure and helps improve your heart failure, but does not cure it. Therefore ENALAPRIL ACTAVIS must be taken every day. Continue taking ENALAPRIL ACTAVIS for as long as your doctor prescribes.

If you forget to take it

If it is almost time for 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 tablet(s) as you would normally.

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

Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering to take your tablets, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much ENALAPRIL ACTAVIS. Do this even if there are no signs of discomfort or poisoning.

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

While you are using ENALAPRIL ACTAVIS

Things you must do

Have your blood pressure checked when your doctor says, to make sure ENALAPRIL ACTAVIS is working.

If you feel any light headedness or dizziness after you take your first dose of ENALAPRIL ACTAVIS or if your dose is increased, tell your doctor immediately. This is especially important if you are taking ENALAPRIL ACTAVIS for heart failure.

If you feel light-headed, dizzy or faint, get up slowly when getting out of bed or standing up.

You may feel light-headed or dizzy, especially if you are also taking a diuretic (fluid tablet). This may be because your blood pressure is falling suddenly. Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this

problem gets worse or continues, talk to your doctor.

If you become pregnant while taking ENALAPRIL ACTAVIS, tell your doctor immediately.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking ENALAPRIL ACTAVIS.

If you plan to have surgery (even at the dentist) that needs a general anaesthetic, tell your doctor or dentist that you are taking ENALAPRIL ACTAVIS.

Your blood pressure may drop suddenly.

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

If you do not drink enough water while taking ENALAPRIL ACTAVIS, you may faint or feel light-headed or sick. This is because your blood pressure is dropping suddenly. If you continue to feel unwell, tell your doctor.

If you have excessive vomiting and/ or diarrhoea while taking ENALAPRIL ACTAVIS, tell your doctor.

This can also mean that you are losing too much water and salt, and may drop your blood pressure too much.

Go to your doctor regularly for a check-up.

Your doctor may occasionally do a blood test to check your potassium level in the blood and to see how your kidneys are working.

Things you must not do

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

Things to be careful of

Be careful driving or Operating machinery until you know how ENALAPRIL ACTAVIS affects you.

ENALAPRIL ACTAVIS 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 ACTAVIS 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.

Side Effects

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

ENALAPRIL ACTAVIS helps most people with high blood pressure and heart failure, 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 treatment if you get some of the side effects.

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

Tell your doctor if you notice any of the following and they worry you:

- 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

These are usually mild side effects of ENALAPRIL ACTAVIS, but may be serious.

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

- 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.

These may be serious side effects. You may need urgent medical attention.

Serious side effects are rare.

If any of the following happen, stop taking ENALAPRIL ACTAVIS and tell your doctor immediately or go to accident and emergency at your nearest hospital:

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

These are serious side effects. You may need urgent medical attention or hospitalisation.

All of these side effects are rare.

Other side effects not listed above may also 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.

After using ENALAPRIL ACTAVIS

Storage

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

If you take the tablets out of the blister pack and store them in another container they will not keep well and they may become soft and crumbly.

ENALAPRIL ACTAVIS Tablets should be kept in a cool dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

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 ENALAPRIL ACTAVIS or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product Description

What it looks like

ENALAPRIL ACTAVIS comes in three types of tablets:

Enalapril Maleate tablets are white to off white, round, flat-face beveled edge tablets with a breakline on one side and “5”, “10” or “20” debossed on the other side.

A box of ENALAPRIL ACTAVIS contains 30 tablets.

Ingredients

Active ingredient:

- ENALAPRIL ACTAVIS - 5 mg enalapril maleate per tablet
- ENALAPRIL ACTAVIS - 10 mg enalapril maleate per tablet
- ENALAPRIL ACTAVIS - 20 mg enalapril maleate per tablet

Inactive ingredients:

- Maleic acid
- Lactose
- Hypromellose
- Croscarmellose sodium
- Sodium stearyl fumarate
- Water-purified

ENALAPRIL ACTAVIS does not contain gluten, sucrose, tartrazine or any other azo dyes.

Name & Address of Sponsor

Amneal Pharma Australia Pty Ltd
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Australia

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ENALAPRIL ACTAVIS 20 mg tablets – AUST R 196513