

AUSPRIL

enalapril maleate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about AUSPRIL tablets.

It does not contain all the available information about this medicine.

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 AUSPRIL against the benefits he/she expects it will have for you.

Ask your doctor or pharmacist if you have any concerns about taking this medicine.

Keep this leaflet with the medicine. You may need to read it again.

What is AUSPRIL

The name of your medicine is AUSPRIL.

The active ingredient is called enalapril maleate.

Enalapril maleate belongs to a group of medicines called the Angiotensin Converting Enzyme (ACE) inhibitors, which are used for the treatment of hypertension and heart failure.

AUSPRIL is available as 5 mg, 10 mg and 20 mg tablets.

What AUSPRIL is used for

AUSPRIL lowers high blood pressure, a condition which doctors call "hypertension". It is also used to treat heart failure.

Hypertension (high blood pressure) is when your blood pressure stays at a

high level than what is needed, even when you may be calm and relaxed.

There are usually no symptoms of hypertension. The only way you will know if you have the condition is to have your blood pressure checked by your doctor on a regular basis.

If high blood pressure is not treated, it can lead to serious health problems such as stroke, heart disease and kidney failure.

AUSPRIL will help to lower your blood pressure.

Heart failure is the condition where the heart muscle is unable to pump strongly enough blood to different tissues throughout the body.

Heart failure may start with no symptoms, but as the condition progresses, patients may feel short of breath or may get tired during activities such as walking. Some patients may wake up at night with a shortness of breath. In different parts of the body, fluid may also collect such as in the ankles and feet, causing them to swell.

AUSPRIL will help to treat heart failure, whether you have any symptoms or not.

In many patients with heart failure who have had symptoms, AUSPRIL may slow the progression of heart failure and reduce the need to go to hospital due to the heart failure. AUSPRIL may also help some of these patients live longer.

In many patients with heart failure who have had no symptoms, AUSPRIL may help to reduce the weakening heart muscle. The medicine 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 to stay at hospital due to heart failure.

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

When used to treat heart failure, AUSPRIL is usually used with other medicines called diuretics or fluid tablets. These medicines help the kidney to eliminate any excess fluids from the body.

How it works

One of the ways AUSPRIL helps lower blood pressure and treats heart failure is that it widens the blood vessels. This means that blood is able to pass more easily through the blood vessels, limiting its efforts in pumping blood around the body. This means that the heart is able to cope better when extra demands are placed on the heart.

Use AUSPRIL only as directed and consult a health care professional if pain or symptoms persist.

Your doctor may have prescribed AUSPRIL for another condition.

Ask your doctor if you have any questions about why it has been prescribed for you.

If you have any concerns, you should discuss this with your doctor.

AUSPRIL tablets are only available with a doctor's prescription.

This medicine is not addictive.

Before you take AUSPRIL

When you must not take it

Do not take AUSPRIL if you are allergic to:

- Enalapril maleate or any other 'ACE inhibitors' used for high blood pressure or heart failure such as 'Amprace' (Another brand of enalapril maleate).
- Any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction to AUSPRIL may include skin rash, itchiness, shortness of breath, swelling of the face, lips or tongue, muscle pain or tenderness or joint pain.

You must tell your doctor if:

- **You are pregnant or intend to become pregnant.**
AUSPRIL is rated in Australia as a Category D drug for the use in pregnancy. It is **not** recommended for use during pregnancy.
If a patient becomes pregnant while on ACE inhibitors, she must immediately inform her doctor to discuss a change in medication and further management.
When taken during the second and third trimesters, ACE inhibitors cause a range of abnormalities including renal dysfunction and oligohydramnios. These can be associated with fetal death in utero.
- **You are breast-feeding or intend to breast-feed.**
AUSPRIL is distributed in breast milk so it is **not** recommended for nursing mothers.
- **You are also taking an anti-inflammatory drug (NSAID or COX-2 inhibitor) and a thiazide diuretic.**

Do not take AUSPRIL if you have ever experienced excessive swelling of the face, lips, mouth, tongue,

throat, hands or feet, for no apparent reason.

Do not take AUSPRIL after the expiry date (EXP.) printed on the pack.

If you take this medicine after the expiry date has passed, it may have no effect at all, or worse, there may be an entirely unexpected effect.

Do not take AUSPRIL if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to take it

You must tell your doctor if:

1. **You are allergic to any other medicines or any foods, dyes or preservatives.**
2. **You have or have had any other medical conditions/ health problems, especially the following:**
 - Kidney disease, or are undergoing dialysis
 - Heart problems
 - Diabetes
 - You are following a very low salt diet

If you have not told your doctor about any of the above, tell him or her before you start taking AUSPRIL.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some of these medicines may interfere with AUSPRIL.

These include:

- Cardiovascular drugs, used to treat heart problems
- 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

- Non-steroidal anti-inflammatory medicines used to relieve pain, swelling, and other symptoms of inflammation

The above medicines may reduce the effectiveness of AUSPRIL, reduce its own effectiveness, and/or react with AUSPRIL resulting in untoward or sometimes dangerous side effects.

This list is not exhaustive. Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking AUSPRIL.

In the future, before you start to take any other medicine, tell your doctor or pharmacist that you are taking AUSPRIL.

How to take AUSPRIL

Follow your doctor's instructions carefully, as they may differ from the information contained in this leaflet.

If you do not understand the instructions in this leaflet, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how many tablets you need to take each day. This depends upon your condition and whether you are taking 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 2.5 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.

How to take it

Swallow AUSPRIL tablets with a glass of water or other liquid.

It does not matter if you take the tablets before or after food.

When to take it

Take your tablets at about the same time each day. This will have the best effect. It will also help you remember when to take them.

How long to take it

AUSPRIL helps control your high blood pressure and helps improve your heart failure, but it does not cure it. THEREFORE, your tablets must be taken every day.

Continue taking AUSPRIL tablets as long as your doctor recommends it.

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 your dose as soon as you remember, and then go back to taking it 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 unsure about whether to take your next dose, speak to your doctor or pharmacist.

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) for advice, or go to casualty at your nearest hospital, if you think that you or anyone else may have taken too much AUSPRIL. Do this even if there are no signs of discomfort or poisoning. Also, report any other medicine or alcohol that has been taken. You may need urgent

medical attention. Keep telephone numbers for these places handy.

If you take too much AUSPRIL, you may have the following symptoms: light-headedness or dizziness or faintness.

While you are using it

Things you must do

Immediately stop taking AUSPRIL if a skin rash or other allergic reaction occurs.

Use your medicine exactly as directed or as your doctor has prescribed.

Tell your doctor if you feel it is not helping your condition.

Have your blood pressure checked when your doctor tells you to, to make sure AUSPRIL is working for you.

Tell your doctor immediately if you are feeling any light-headedness, dizziness, or faintness while you are taking this medicine.

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

Tell your doctor immediately if you become pregnant while you are taking AUSPRIL.

Tell your doctor and pharmacist that you are taking AUSPRIL, if you are about to be started on any new medication.

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

Drink enough water during exercise and in hot weather when you are taking AUSPRIL, especially if you sweat a lot.

If you start to have excessive vomiting and/or diarrhea occurring while you are taking this medicine, tell your doctor immediately.

Visit your doctor regularly. Your doctor needs to check your progress

and see whether you need to stop taking AUSPRIL.

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

Always discuss with your doctor any problems or difficulties during or after taking AUSPRIL.

Things you must not do

Do not take any other medicines while you are taking AUSPRIL without first telling your doctor.

Do not give this medicine to anyone else, even if his or her symptoms seem similar to yours.

Do not drive or operate machinery until you know how AUSPRIL affects you.

AUSPRIL 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 this medicine 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 become worse.

Below are some suggested self-help measures that may help improve your condition.

Talk to your doctor or pharmacist about these measures and for any more information you may need.

- 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. Before you start any exercise, ask your doctor for the most suitable program for you.

- Salt - your doctor may advise you to monitor 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 reduce your intake.
- Weight - your doctor may suggest you to lose some weight, so that you are able to help lower your blood pressure. 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 AUSPRIL.

It helps most people with high blood pressure and heart failure, but it may have unwanted side effects in some people.

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

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

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

- light-headedness or dizziness due to low blood pressure
- depression, dream abnormality or hallucinations
- headache
- fatigue
- dry cough
- mild stomach upsets such as feeling sick, diarrhoea, or stomach pains
- muscle cramps

These side effects are usually mild, but may become serious.

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

- changes in the way your heart beats, for example, if you notice it is 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

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

Serious side effects are rare.

If any of the following occur, stop taking AUSPRIL and tell your doctor immediately or go to casualty 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 nettlerash
- 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.

Some people may get other side effects when taking AUSPRIL.

Check with your doctor as soon as possible if you have any problems while taking this medicine even if you do not think the problems are connected with the medicine or in the leaflet.

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

After using it

Storage

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

Keep AUSPRIL in a cool dry place where the temperature stays below 25°C and protect it from light and moisture.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half meters above the floor is a good place to store medicines.

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

Do not leave it in the car or on windowsills.

Heat and dampness can destroy some medicines.

Do not take AUSPRIL if the tablets do not look quite right.

Disposal

If your doctor tells you to stop taking your medicine OR it has passed its expiry date, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

AUSPRIL tablets (oral) are available in three different strengths and each of them has a different appearance:

AUSPRIL 5 mg tablets:

White to off-white barrel-shaped tablet, embossed with EL 'bisect' 5 on one side and the Arrow logo, ">" on the other side.

AUSPRIL 10 mg tablets:

Salmon barrel-shaped tablet, embossed with EL 'bisect' 10 on one side and the Arrow logo, ">" on the other side.

AUSPRIL 20 mg tablets:

Peach barrel-shaped tablet, embossed with EL 'bisect' 20 on one side and the Arrow logo, ">" on the other side.

Ingredients

Active ingredient:

- Enalapril maleate

Inactive ingredients: AUSPRIL 5 mg, 10 mg and 20 mg tablets contain:

- lactose
- sodium bicarbonate
- starch-maize
- starch-pregelatinised maize
- magnesium stearate
- croscarmellose sodium
- iron oxide red (10 mg and 20 mg)
- iron oxide yellow (10 mg)

AUSPRIL does NOT contain gluten, sucrose, tartrazine or any other azo dyes.

Sponsor

Aspen Pharma Pty Ltd
34-36 Chandos Street
St Leonards NSW 2065
Australia

The Australian Registration Numbers are:

- **AUSPRIL 5 mg** AUST R
121758
- **AUSPRIL 10 mg** AUST R
121757
- **AUSPRIL 20 mg** AUST R
121756

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