

FOSIPRIL®

Fosinopril Sodium

Consumer Medicine Information

What is in this leaflet

Read this leaflet carefully before taking FOSIPRIL.*

This leaflet answers some common questions about FOSIPRIL. It does not contain all the available information. Some of the information it contains may not apply to you. It does not take the place of talking to your doctor or pharmacist.

Keep this leaflet.

You may need to refer to it again later.

If you have any concerns about taking FOSIPRIL, ask your doctor or pharmacist.

What is FOSIPRIL used for

FOSIPRIL is used for treating high blood pressure (hypertension) or heart failure. Both of these are long term (chronic) diseases so it is important that you continue to take your FOSIPRIL every day.

High blood pressure (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. If you have hypertension (high blood pressure), this means that your blood pressure stays higher than is needed, even when you are 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, including 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. Heart failure may start off with no symptoms, but as the condition progresses, patients 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.

How FOSIPRIL works

FOSIPRIL contains fosinopril sodium. Fosinopril sodium belongs to a class of medicines known as ACE inhibitors. It works by widening your blood vessels, reducing the pressure in the vessels (reducing 'blood pressure') and by making it easier for your heart to pump blood around your body. This helps your heart to work better by increasing the supply of oxygen to your heart.

Your doctor may have prescribed FOSIPRIL for another reason.

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

FOSIPRIL is not addictive.

FOSIPRIL is available only with a doctor's prescription.

The safety and effectiveness of FOSIPRIL in children has not been established.

Before you take FOSIPRIL

When you must not take it

Do not take FOSIPRIL if:

- you have an allergy to fosinopril sodium (the active ingredient in FOSIPRIL), or to any of the inactive ingredients listed at the end of this leaflet.

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

- you have taken any other 'ACE inhibitor' medicine 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 medicine before, you may be allergic to FOSIPRIL.

- you have a history of angioedema or angioneurotic oedema, which is swelling of the face, lips, tongue, throat (which may cause difficulty in swallowing or breathing), hands or feet, for no apparent reason.

Do not take FOSIPRIL if you are pregnant or are trying to become pregnant.

FOSIPRIL may cause serious injury to your developing baby if you take it during pregnancy.

Do not take FOSIPRIL if you are breastfeeding or intend to breastfeed.

Do not take FOSIPRIL after the expiry date printed on the pack.

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

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

Do not take FOSIPRIL if the tablets change in appearance, colour or taste.

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

Before you start to take FOSIPRIL

Tell your doctor if you have allergies to:

- any other medicine
- any other substances, such as foods, preservatives or dyes

Tell your doctor if you have a family history of swelling of the face, lips, tongue, throat that may cause difficulty in swallowing or breathing.

Tell your doctor if you have any medical conditions, especially the following:

- diabetes
- take any other medicines or drugs including any immunosuppressant medicine or trimethoprim containing medicines
- kidney problems, or have had kidney problems in the past, or are having dialysis
- liver problems, or have had liver problems in the past

- low blood pressure, which you may notice as dizziness or lightheadedness
- are going to have surgery (including dental surgery) involving a general anaesthetic, even if it is minor

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

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

Taking other medicines

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

Some medicines can affect the way FOSIPRIL works. It is especially important that you tell your doctor if you are taking any of the following:

- water tablets or diuretics (for example Lasix[®], Urex[®], Natrilix[®], Moduretic[®])
- lithium or lithium-containing preparations (for example Lithicarb[®], Priadel[®])
- potassium tablets (for example SPAN-K[®], SLOW-K[®] or MAG-K[®])
- potassium-containing salt substitutes (for example PRESSOR-K[®])
- antacids
- if you are taking FOSIPRIL for high blood pressure do not take any medicine (including ones bought without prescription) for appetite control, asthma, colds, coughs, hayfever or sinus problems unless you have discussed the medicine with your doctor or pharmacist.
- aspirin
- anti-inflammatory medicines (these are used to relieve pain, swelling and other symptoms of inflammation, including arthritis)

and include nonsteroidal anti-inflammatory agents - NSAIDs (for example Voltaren, Indocid) and COX-2 inhibitors (for example Celebrex). Taking a combination of Fosipril with a thiazide diuretic (fluid tablet) and an anti-inflammatory medicine may damage your kidneys.

- medicines that lower your immune system, such as medicines used to prevent rejection of transplant organs.
- trimethoprim containing medicines (for example Bactrim, Septrim, Alprim) used to treat certain types of infections

Your doctor will decide whether your treatment needs to be altered or whether you should have check ups or blood tests more frequently

How to take FOSIPRIL

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information in this leaflet. Your doctor or pharmacist will tell you how many tablets you will need to take each day.

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

How much to take

FOSIPRIL is usually taken at a dose of 10mg to 40mg once a day. Your doctor may have prescribed a different dose for you.

When to take it

Take FOSIPRIL at about the same time each day.

Taking your tablet at about the same time each day will help you to remember when to take it. It does not matter if you take FOSIPRIL before or after food.

If you need to take an antacid, take it at least 2 hours before or two hours after your dose of FOSIPRIL.

How long to take it

FOSIPRIL helps to control your condition but does not cure it. Therefore you must take FOSIPRIL every day. Continue taking it for as long as your doctor tells you.

If you forget to take FOSIPRIL

If you forget to take one or more doses of FOSIPRIL, if it is almost time for your next dose, skip the dose you missed and take your next dose at the normal time and in the normal amount.

Otherwise take it 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. Do not take any more than your doctor prescribed for you.

If you are not sure what to do, ask your doctor or pharmacist. If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much FOSIPRIL

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

You may need urgent medical attention.

Things you must do

Tell any other doctors, dentists and pharmacists who are treating you that you are taking FOSIPRIL.

If you are about to be started on a new medicine, tell your doctor, dentist or pharmacist that you are taking FOSIPRIL. 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 FOSIPRIL or if your dose is increased.

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

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

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking FOSIPRIL.

Having a general anaesthetic while taking FOSIPRIL may also cause your blood pressure to drop suddenly.

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

If you are about to have blood tests, tell your doctor that you are taking FOSIPRIL.

FOSIPRIL may interfere with the results of some tests.

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

Go to your doctor regularly for a check-up.

Your doctor may like to do blood tests to see how FOSIPRIL is affecting you.

Things you must not do

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

Do not take FOSIPRIL to treat any other complaints unless your doctor or pharmacist tells you to.

Do not stop taking FOSIPRIL, or lower the dosage, without checking with your doctor.

Things to be careful of

As with other ACE inhibitor medicines, you may feel light-headed or dizzy when you begin to take FOSIPRIL or after your dose is increased. This is because your blood pressure is dropping suddenly.

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

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. Be careful the first time you take FOSIPRIL, especially if you are elderly.

Be careful driving or operating machinery until you know how FOSIPRIL affects you.

As with other ACE inhibitor medicines, FOSIPRIL may cause dizziness, or light-headedness in some people. Make sure you know how you react to FOSIPRIL before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs do not drive

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

Things that would be helpful for your blood pressure

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.

• **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.

• **Diet -**

eat a healthy low-fat diet which includes plenty of fresh vegetables, fruit, bread, cereals and fish. Also eat less fat and sugar.

• **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.

• **Exercise -**

regular exercise helps to reduce blood pressure and helps to get the heart fitter, but it is important not to overdo it. Walking is good exercise, but try to find a route that is reasonably flat. Before starting any exercise, ask your doctor about the best kind of programme for you.

• **Smoking -**

your doctor may advise you to stop smoking or at least cut down.

Side effects

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

FOSIPRIL helps most people with high blood pressure, 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.

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

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

- feeling lightheaded, dizzy or faint
- headache
- tiredness, fatigue or weakness
- dry cough
- feeling sick (nausea) or vomiting
- upset stomach (dyspepsia) or heartburn
- diarrhoea
- stomach pains
- muscle cramps or pains

These are the more common side effects of FOSIPRIL. (Mostly these are mild and short lived).

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

- changes to your heart rhythm
- infections of your urinary tract or upper respiratory tract (URTI, or cold or flu symptoms)
- severe dizziness (vertigo)
- impotence (inability to get or maintain an erection)
- mild rash or itching
- gout (painful, swollen joints)
- diabetes (symptoms include - excessive thirst, greatly increased amount of urine, increase of appetite with a loss of weight, feeling tired, drowsy, weak, depressed, irritable and generally unwell)
- sore throat and fever
- hepatitis (symptoms include - nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes and dark coloured urine)

- confusion; irregular heartbeat; nervousness; numbness or tingling of the hands, feet or lips; shortness of breath or difficulty breathing; weakness or heaviness of legs. (You may experience these symptoms if too much potassium builds up in your body.)

These are serious side effects. You may need medical attention. Serious side effects are rare.

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

- Swollen face, swollen lips, swollen mouth, swollen throat, swollen hands or feet
- if you faint or if your skin turns yellow
- sore throat and fever
- chest pain
- difficulty breathing
- itchy skin and/or rash
- not urinating (passing water) as much as usual
- stomach pain with or without nausea

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

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects.

You may not experience any of them

After using FOSIPRIL

Storage

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

If you take the tablets out of the pack they will not keep well.

Keep FOSIPRIL tablets in a cool dry place, in the dark, where the temperature stays below 25°C.

Do not store FOSIPRIL or any other medicine in the bathroom or near a sink. Do not leave it in the car on hot days 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 FOSIPRIL or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Australian registration numbers:

FOSIPRIL 10 - AUST R 100059

FOSIPRIL 20 - AUST R 100060

Product description

What it looks like:-

FOSIPRIL comes in 2 strengths:

- FOSIPRIL 10 – white oval tablet with ‘FI’, partial score, ‘10’ on one side.
- FOSIPRIL 20 – white capsule-shaped tablet with ‘FI 20’ on one side.

Each pack of FOSIPRIL contains 30 tablets.

Ingredients

The active ingredient in FOSIPRIL is fosinopril sodium:

- each FOSIPRIL 10 tablet contains 10 mg of fosinopril sodium
- each FOSIPRIL 20 tablets contains 20 mg of fosinopril sodium.

FOSIPRIL tablets also contain:

- lactose monohydrate
- microcrystalline cellulose
- crospovidone
- povidone
- glyceryl behenate.

Sponsor

Arrow Pharma Pty Ltd
15 – 17 Chapel Street
Cremorne VIC 3121

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