

FOSIPRIL

fosinopril sodium

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about FOSIPRIL.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you using FOSIPRIL against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

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

What is it used for

FOSIPRIL belongs to a group of medicines called angiotensin converting enzyme (ACE) inhibitors.

FOSIPRIL is used to treat high blood pressure (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 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 including stroke, heart disease and kidney failure.

FOSIPRIL helps lower your blood pressure by widening blood vessels.

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. Some people develop heart failure after having a heart attack. However, there are also other causes of heart failure.

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.

One of the ways FOSIPRIL helps heart failure is by widening the blood vessels, so that the heart does not 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.

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.

There is no evidence that FOSIPRIL is addictive.

FOSIPRIL is available only with a doctor's prescription.

Use in children

FOSIPRIL is not recommended for use in children, as the safety and effectiveness of this drug have not been established in children.

Before you take it

When you must not take it

Do not take FOSIPRIL if you have an allergy to fosinopril sodium or any other medicine containing fosinopril, 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.

Do not take FOSIPRIL if you have taken any other ACE inhibitor medicines, 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 FOSIPRIL.

Do not take it if you or your family have a history of swelling of the face, lips, tongue, throat, hands or feet either spontaneously for no apparent reason or in response to other medicines.

This rare condition is known as angioedema.

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

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

Do not take it if you are breastfeeding. FOSIPRIL passes into breast milk. There is a possibility that the breast-fed baby may be affected.

Do not use it if the expiry date (Exp.) printed on the pack has passed.

Do not use it if the packaging shows signs of tampering or the medicine does not look quite right.

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

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

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

- kidney problems like reduced kidney function or renal artery stenosis, or are having dialysis using certain high-flux membranes (polyacrylonitrile)
- liver problems
- heart problems
- diabetes
- low blood pressure (you may notice this as fainting or dizziness, especially when standing)
- high level of potassium in your blood

- systemic lupus erythematosus (SLE), scleroderma or other autoimmune diseases.

Tell your doctor if you have a family history of swelling of the face, lips, tongue, throat, hands or feet.

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

FOSIPRIL should not be used in pregnancy or breastfeeding.

Tell your doctor if you are going to have surgery (including dental surgery) involving a general anaesthetic, even if it is minor.

Tell your doctor if you are about to receive desensitisation therapy for an allergy.

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

Some medicines may be affected by FOSIPRIL, or may affect how well it works. These include:

- 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 drugs (NSAIDs), medicines used to relieve pain, swelling and other symptoms of inflammation
- antacids
- some medicines used for appetite control
- some medicines used to treat colds, coughs or sinus problems
- medicines that lower your immune system.

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

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

How to take it

How much to take

Your doctor will decide how many tablets you need to take each day. This depends on your condition and whether you are taking other medicines.

High blood pressure

The usual starting dose is 10 mg, taken once a day. This dose may be increased to 40 mg daily.

Heart failure

The usual starting dose is 10 mg, taken once a day. This dose may be increased to 40 mg daily.

Patients with reduced kidney function

The starting dose is 5 to 10 mg, taken once a

day. The maintenance dose will depend on your kidney function.

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

How to take it

Swallow FOSIPRIL with a glass of water.

When to take it

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

Take it 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.

How long to take FOSIPRIL for

Continue taking FOSIPRIL for as long as your doctor prescribes.

The medicine helps control your condition, but does not cure it. So, it is best for you to take FOSIPRIL every day.

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 tablets 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 FOSIPRIL (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the 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.

While you are taking it

Things you must do

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

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

If you feel light-headed or dizzy after taking your first dose of FOSIPRIL, or if your dose is increased, tell your doctor immediately.

This is especially important if you are taking it for heart failure.

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

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

If you do not drink enough water while taking it, you may feel faint, 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 FOSIPRIL, tell your doctor.

You may lose too much water and salt, which may drop your blood pressure too much.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking FOSIPRIL. Your blood pressure may drop suddenly.

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

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

The medicine 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 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 use FOSIPRIL to treat any other conditions unless your doctor tells you to.

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

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

Things to be careful of

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. If this problem gets worse or continues, talk to your doctor.

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

As with other ACE inhibitor medicines, FOSIPRIL 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 it 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

The following self-help measures may help your conditions. Ask your doctor or pharmacist for more information.

- **Alcohol** - your doctor may advise you to limit your alcohol intake.
- **Smoking** - your doctor would 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 reduce the amount of work your heart has to do. Some people may need a dietician's help to lose weight.
- **Diet** - eat a healthy diet, which includes plenty of fresh fruit, vegetables, 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 use minimal amount in cooking and avoid table salt.
- **Exercise** - regular exercise helps reduce blood pressure and helps the heart get fitter, but it is important not to overdo it. Walking is a good exercise. Try to find a route that is fairly flat. Before starting, ask your doctor for the most suitable exercise program for you.

Side effects

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

Like all other medicines, it may have unwanted side effects in some people. 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.

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

You may not experience any of them.

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

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

These side effects of FOSIPRIL are common, but usually mild and short-lived.

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

- changes to your heart rhythm
- severe dizziness (vertigo)
- impotence (inability to get or maintain an erection)
- yellowing of the skin and eyes, dark urine, itching, loss of appetite, feeling unwell/tired (symptoms of jaundice)
- itchy skin rash or other skin problems
- painful, swollen joints (gout)
- signs of worrying or frequent infections such as fever, severe chills, sore throat or mouth ulcers
- passing less or more urine than is normal for you
- mood changes (depressed or irritable)
- high potassium level with symptoms like confusion, nervousness, irregular heartbeat, weakness or numbness of arms or legs.

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

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- swelling of the face, lips, mouth or throat that may cause difficulty in swallowing or breathing
- swelling of the hands, feet or ankles
- pinkish, itchy swellings on the skin (hives, nettle rash)

- chest pain, angina
- not passing urine as much as usual.

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

After using it

Storage

Keep FOSIPRIL 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.

Keep it in a cool dry place where the temperature stays below 25°C.

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

If you take it out of the pack, it may not keep well.

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

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

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop using FOSIPRIL, or your medicine has passed its expiry date, ask your pharmacist what to do with any medicines that are left over.

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

Australian registration numbers:

FOSIPRIL 10 - AUST R 100059

FOSIPRIL 20 - AUST R 100060

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