

Fosetic® 20/12.5 Tablets

contain the active ingredients fosinopril sodium and hydrochlorothiazide

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about FOSETIC 20/12.5. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

If you have any concerns about taking FOSETIC 20/12.5, ask your doctor or pharmacist.

What FOSETIC 20/12.5 is used for

FOSETIC 20/12.5 is used to lower 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.

How FOSETIC 20/12.5 works

FOSETIC 20/12.5 tablets contain two medicines, fosinopril sodium and hydrochlorothiazide. Both medicines reduce blood pressure, but work different ways.

Fosinopril sodium belongs to a group of medicines called angiotensin converting enzyme (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.

Hydrochlorothiazide is a diuretic (fluid tablet). It helps reduce the amount of excess fluid in the body by increasing the amount of urine produced. It also lowers high blood pressure, particularly when combined with other blood pressure reducing medicines such as ACE inhibitors.

Your doctor may have prescribed FOSETIC 20/12.5 for another reason.

Ask your doctor if you have any questions about why FOSETIC 20/12.5 has been prescribed for you.

FOSETIC 20/12.5 is not addictive. FOSETIC 20/12.5 is available only with a doctor's prescription.

The safety and effectiveness of FOSETIC 20/12.5 in children have not been established.

Before you take FOSETIC 20/12.5

When you must not take it

Do not take FOSETIC 20/12.5 if:

- **you have an allergy to fosinopril sodium or hydrochlorothiazide (the active ingredients in FOSETIC 20/12.5), or to any of the inactive ingredients listed at the end of this leaflet**

Symptoms of an allergic reaction to FOSETIC 20/12.5 may include skin rash, itchiness, shortness of breath, swelling of the face, lips, tongue, throat, hands or feet.

- **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 FOSETIC 20/12.5.

- **you have had an allergic reaction to another medicine which contains an ingredient with a name like "sulphonamide" or a "-thiazide" (like hydrochlorothiazide). Ask your doctor or pharmacist if you are not sure**

- 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 FOSETIC 20/12.5 if you are pregnant.

FOSETIC 20/12.5 may affect your developing baby if you take it during pregnancy.

Do not take FOSETIC 20/12.5 if you are not producing any urine (anuric).

Do not take FOSETIC 20/12.5 after the expiry date printed on the pack. Do not take FOSETIC 20/12.5 if the packaging is torn or shows signs of tampering.

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

If you are not sure whether you should start taking FOSETIC 20/12.5, talk to your doctor.

Before you start to take FOSETIC 20/12.5

Tell your doctor if you have allergies to:

- any other medicines
- 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:

- kidney problems, or have had kidney problems in the past, or are having dialysis
- liver problems, or have ever had liver problems in the past
- low blood pressure, which you may notice as dizziness or lightheadedness
- diabetes

- high levels of potassium in your blood (hyperkalaemia)
- systemic lupus erythematosus (SLE), scleroderma or other autoimmune diseases
- gout
- have a problem passing urine
- are going to have surgery (including dental surgery) involving a general anaesthetic, even if it is minor

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

If you have not told your doctor about any of the above, tell them before you start taking FOSETIC 20/12.5.

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 and FOSETIC 20/12.5 may interfere with each other. These include:

- water tablets or diuretics (for example Lasix®, Urex®, Natrilix®, Moduretic®)
- other medicines used to treat high blood pressure
- lithium or lithium-containing medicine (for example Lithicarb®, Priadel®)
- potassium tablets (for example Span-K®, Slow-K® or Mag-K®)
- potassium-containing salt substitutes (for example Pressor-K®)
- antacids
- arthritis/osteoarthritis tablets which are called non-steroidal anti-inflammatory drugs (NSAIDS) (for example Voltaren®, Indocid®)
- alcoholic drinks
- sleeping tablets
- strong pain relieving medicines
- antidiabetic medicines (for example insulin)

- medicines or other tablets containing calcium
- antigout medicines (for example Anturan®, Benamid®, Capurate®)
- cholestyramine resin and colestipol hydrochloride medicines to treat high cholesterol (for example Questran® Lite, Colestid® Granules)
- some medicines used during surgery or emergency situations, such as anaesthetics
- medicines that lower your immune system, such as corticosteroids, cyclosporin or medicines used to treat cancer (including radiation therapy)
- 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 FOSETIC 20/12.5 and an anti-inflammatory medicine may damage your kidneys.

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

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking FOSETIC 20/12.5

How to take FOSETIC 20/12.5

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 pack, ask your doctor or pharmacist for help.

How much to take

FOSETIC 20/12.5 tablet is not scored and must not be broken.

Since there is no lower dose (10/12.5 mg) of FOSETIC available, if a dose of fosinopril/hydrochlorothiazide 10/12.5 mg is required, an alternative product must be used.

FOSETIC 20/12.5 is usually taken at a dose of one 20/12.5 mg tablet per day. Your doctor may have prescribed a different dose for you.

When to take it

Take FOSETIC 20/12.5 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 FOSETIC 20/12.5 before or after food.

If you need to take an antacid (or Questran® Lite or Colestid® Granules), take it at least 2 hours before or two hours after your dose of FOSETIC 20/12.5

How long to take it

FOSETIC 20/12.5 helps to control your condition but does not cure it. Therefore you must take FOSETIC 20/12.5 every day. Continue taking it for as long as your doctor tells you .

If you forget to take FOSETIC 20/12.5

If you forget to take one or more doses of FOSETIC 20/12.5, take your next dose at the normal time and in the normal amount.

Do not take a double dose to make up for the dose that you missed. Do not take more than your doctor has prescribed for you

If you take too much FOSETIC 20/12.5

Immediately phone 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 FOSETIC 20/12.5. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking FOSETIC 20/12.5

Things you must do

Tell any other doctors, dentists and pharmacists who are treating you that you are taking FOSETIC 20/12.5.

If you are about to be started on a new medicine, tell your doctor, dentist or pharmacist that you are taking FOSETIC 20/12.5. 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 FOSETIC 20/12.5 or if your dose is increased.

Make sure you drink enough water during exercise and hot weather when you are taking FOSETIC 20/12.5, especially if you sweat a lot.

If you do not drink enough water while taking FOSETIC 20/12.5, 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 FOSETIC 20/12.5.

Having a general anaesthetic while taking FOSETIC 20/12.5 may also cause your blood pressure to drop suddenly.

If you become pregnant while taking FOSETIC 20/12.5, tell your doctor immediately.

If you are about to have blood tests, tell your doctor that you are taking FOSETIC 20/12.5.

FOSETIC 20/12.5 may interfere with the results of some tests.

Have your blood pressure checked when your doctor says, to make sure FOSETIC 20/12.5 is working.

Go to your doctor regularly for a check-up.

Your doctor may like to do blood tests to see how FOSETIC 20/12.5 is affecting you.

Things you must not do

Do not give FOSETIC 20/12.5 to anyone else, even if they have the same condition as you.

Do not take FOSETIC 20/12.5 to treat any other complaints unless your doctor or pharmacist tells you to.

Do not stop taking FOSETIC 20/12.5, 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 FOSETIC 20/12.5 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 FOSETIC 20/12.5, especially if you are elderly.

Be careful driving or operating machinery until you know how FOSETIC 20/12.5 affects you.

As with other ACE inhibitor medicines, FOSETIC 20/12.5 may cause dizziness, or light-headedness in some people. Make sure you know how you react to FOSETIC 20/12.5 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 program 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 FOSETIC 20/12.5.

FOSETIC 20/12.5 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**

- **sore throat or runny nose**
- **feeling sick (nausea) or vomiting**
- **upset stomach (dyspepsia) or heartburn**
- **diarrhoea**
- **stomach pains**
- **muscle cramps or pains**
- **flushing**
- **any problem urinating (passing water)**

These are the more common side effects of FOSETIC 20/12.5. (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)**

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

If any of the following happen, stop taking FOSETIC 20/12.5 and either tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- **fainting within a few hours of taking a dose of FOSETIC 20/12.5**

- swelling to the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing; swelling of the hands or feet; severe itching and/or rash
- difficulty breathing
- not urinating (passing water)
- chest pain
- stomach pain with or without nausea

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

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that makes you feel unwell while you are taking FOSETIC 20/12.5.

After using FOSETIC 20/12.5

Storage

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

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

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

Do not store FOSETIC 20/12.5 or any other medicine in the bathroom or near a sink.

Do not leave it on a window sill or in a car on hot days.

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 or pharmacist tells you to stop taking FOSETIC 20/12.5 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

FOSETIC 20/12.5 tablets are light orange coloured, round tablets with "FH" on one side. FOSETIC 20/12.5 is available in blister packs of 30 tablets.

Ingredients

Active ingredients:

FOSETIC 20/12.5 tablets contain 20mg of fosinopril sodium and 12.5 mg hydrochlorothiazide.

Other ingredients:

- lactose
- croscarmellose sodium
- starch- pregelatinised maize
- glycerol dibehenate
- pigment blend PB-23061orange

Sponsor

FOSETIC 20/12.5 is supplied in Australia by:

Sigma Pharmaceuticals Pty Ltd

117 Harrington St.
The Rocks, Sydney NSW 2000
Australia
Telephone: 1800 065 772

Distributor

Sigma Pharmaceuticals (Australia) Pty Ltd

96 Merrindale Drive
Croydon VIC 3136
Australia

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AUST R 143587

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