

APO-Fosinopril

Contains the active ingredient *fosinopril sodium*

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about fosinopril. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

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

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

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

What this medicine is used for

The name of your medicine is APO-Fosinopril. It contains the active ingredient fosinopril.

It is used to treat:

- high blood pressure (hypertension)
- heart failure.

Both of these are long term (chronic) diseases so it is important that you continue to take your medicine 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.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed this medicine for another reason.

This medicine is available only with a doctor's prescription.

How it works

Fosinopril belongs to a class of medicines known as 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, so that when you place extra demands on your heart, such as during exercise, your heart may cope better and you may not get short of breath as easily.

There is no evidence that this medicine is addictive.

Use in children

This medicine should not be used in children.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You are pregnant.**
Fosinopril may affect your developing baby if you take it during pregnancy.
- 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, associated with previous treatment of ACE inhibitors.
- You take aliskiren-containing medications (for high blood pressure) and have diabetes or kidney problems.
- **You have had an allergic reaction to fosinopril, any other ACE inhibitor or any of the ingredients listed at the end of this leaflet.**
Symptoms of an allergic reaction may include cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body, rash, itching or hives on the skin; fainting or hayfever-like symptoms
If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.
- **The expiry date (EXP) printed on the pack has passed.**
- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - family history of swelling of the face, lips, tongue, throat that may cause difficulty in swallowing or breathing
 - diabetes

- are undertaking any immunosuppressive therapy
 - are taking trimethoprim containing medicines
 - kidney problems, or are having dialysis
 - liver problems
 - low blood pressure, which you may notice as dizziness or lightheadedness
 - you are following a very low salt diet
 - you are dehydrated, or have recently suffered from excessive vomiting or diarrhoea.
 - coughing or skin reactions if you have taken other ACE inhibitors in the past.
3. You are currently breastfeeding or you plan to breastfeed. Do not take this medicine whilst breastfeeding.
 4. You are planning to have surgery or an anaesthetic.
 5. You are currently receiving or are planning to receive dental treatment.
 6. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Taking other medicines

Some medicines may interact with fosinopril. These include:

- water tablets or diuretics (for example frusemide, indapamide, amiloride and hydrochlorothiazide)
- potassium tablets (for example potassium chloride)
- potassium-containing salt substitutes
- angiotensin II receptor blockers (e.g. irbesartan, valsartan, telmisartan) or aliskiren-containing medications
- diabetes medication
- lithium or lithium-containing preparations (for example lithium carbonate)
- antacids
- if you are taking fosinopril 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
- anti-inflammatory medicines (these are used to relieve pain, swelling and other symptoms of inflammation, including arthritis) and include non-steroidal anti-inflammatory agents - NSAIDS (for example diclofenac and aspirin) and COX-2 inhibitors (for example celecoxib). Taking a combination of fosinopril with a thiazide diuretic (water 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 used to treat certain types of infections
- injectable gold or sodium aurothiomalate.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with fosinopril.

How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

How to take it

Most people will initially start taking a 10 mg dose once daily. Fosinopril is then usually taken at a dose of 10 mg to 40 mg once a day. Your doctor may have prescribed a different dose for you.

When to take it

Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

It does not matter if you take it before, with or after food.

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

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. Otherwise take it as soon as you remember and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for missed doses.

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.

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 fosinopril or if your dose is increased.

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

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

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours
- Take your medicine to treat any other condition unless your doctor tells you to
- Stop taking your medicine, or change the dosage, without first 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 fosinopril 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 fosinopril, especially if you are elderly.

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

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

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking fosinopril or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

- feeling light-headed, 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
- taste disturbance.

Tell your doctor as soon as possible if you notice any of the following: These may be serious side effects. You may need medical attention.

- changes to your heart rhythm
- infections of your urinary tract, upper respiratory tract, 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).

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

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

- fluid filled blisters or itchy rash, especially if it appears quickly
- if you faint or if your skin turns yellow
- sore throat and fever
- chest pain
- not urinating (passing water) as much as usual
- stomach pain with or without nausea.

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to fosinopril, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing.
- swelling of the face, lips, tongue, or other parts of the body
- rash, itching or hives on the skin
- fainting
- hayfever-like symptoms.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine 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 this medicine or they have passed their expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Fosinopril looks like

10 mg tablets:

White, capsule shaped biconvex tablets with indents, engraved APO on one side and FOS-10 on the side.

20 mg tablets:

White, oval, biconvex tablets, engraved APO on one side and FOS-20 on the side.

Fosinopril 10mg and 20mg tablets are packaged in blister packs and bottles of 30 tablets*.

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each tablet contains 10 mg or 20 mg of Fosinopril sodium as the active ingredient.

It also contains the following inactive ingredients:

- lactose
- crospovidone
- zinc stearate.

Contains sugars as lactose. This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APO-Fosinopril 10 mg tablet blister pack: AUST R 119874

APO-Fosinopril 10 mg tablet bottle: AUST R 119875

APO-Fosinopril 20 mg tablet blister pack: AUST R 119876

APO-Fosinopril 20 mg tablet bottle: AUST R 119877

Sponsor

Arrotex Pharmaceuticals Pty Ltd
15-17 Chapel Street
Cremorne VIC 3121
Australia

Web: www.arrotex.com.au

APO and APOTEX are registered trade marks of Apotex Inc.

This leaflet was prepared in:
February 2023.