

APO-Fosinopril HCTZ

Contains the active ingredients, Fosinopril sodium and Hydrochlorothiazide

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

Consumer Medicine Information

What is in this leaflet

Read this leaflet carefully before taking your medicine Ask your doctor or pharmacist if you do not understand anything or are worried about taking your medicine.

This leaflet answers some common questions about Fosinopril HCTZ. 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. Some more recent information on your medicine may be available. Speak to your pharmacist or doctor to obtain the most up-to-date information.

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.

Keep this leaflet with your medicine.

You may want to read it again.

What Fosinopril HCTZ is used for

The name of your medicine is APO-Fosinopril HCTZ. It contains the active ingredients, Fosinopril sodium and Hydrochlorothiazide.

It 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. 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 it works

These tablets contain two medicines, Fosinopril sodium and hydrochlorothiazide. Both medicines reduce blood pressure, but work in 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. 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.

Together Fosinopril and hydrochlorothiazide lower high blood pressure.

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

Your doctor may have prescribed it for another reason.

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

There is no evidence that this medicine is addictive.

This medicine may affect your ability to drive a car or operate machinery. It may make you feel dizzy or light-headed, so wait to see if it affects you before you drive a car, operate machinery, or do anything else that could be dangerous if you are not completely alert. If this occurs do not drive.

Use in children

There is not enough information to recommend the use of this medicine in children.

Before you take Fosinopril HCTZ

When you must not take it

Do not take this medicine if:

- You have had an allergic reaction to Fosinopril (or other ACE inhibitors) or hydrochlorothiazide (or other thiazides), or sulphonamides (possible cross-reaction) or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include: shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; muscle pain or tenderness or joint pain; or rash, itching or hives on the skin.

- You have taken any other "ACE inhibitor" medicine before and it caused you to develop swelling of the face, lips, hands/ feet, or breathing difficulties
- You have a history of angioedema, or angioneurotic oedema, which is swelling of the face, lips, tongue, throat (leading to difficulty swallowing or breathing), hands or feet, for no apparent reason.
- You are not producing urine (anuric)

Do not take this medicine if you are pregnant or plan to become pregnant.

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

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

If you take this medicine after the expiry date has passed, it may not work as well.

Do not take this medicine if the packaging is torn, shows signs of tampering or if it does not look quite right.

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

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

Before you start to take it

Tell your doctor if:

1. You have allergies to:

- any other medicines containing ACE inhibitors, thiazides or sulphonamides
- any other substances, such as foods, preservatives or dyes.

2. You have or have had any medical conditions, especially the following:

- a family history of swelling of the face, lips, tongue, throat that may cause difficulty in swallowing or breathing
- systemic lupus erythematosus or scleroderma or other autoimmune disease
- gout
- dehydration (e.g. recent diarrhoea and/or vomiting)
- diabetes
- problems passing urine
- kidney or liver problems (either now, or in the past)
- very high blood pressure
- heart problems
- renal arterial stenosis
- increased or decreased levels of sodium, potassium or chloride
- low blood pressure

3. Any of the following applies to you:

- You are on a low salt diet
- You are over 65 years of age

- You have had a kidney transplant or are on haemodialysis
- You are about to have a treatment called LDL apheresis
- You are going to have desensitisation treatment (e.g. treatment to reduce the effects of an allergy to bee or wasp stings).
- You are going to have surgery (including dental surgery) involving a general anaesthetic, even if it is minor
- You plan to have a blood or urine test

4. You plan to become pregnant or breast-feed.

Your doctor will discuss with you alternative medicines to take when pregnant, as it may affect your developing baby if you take it during pregnancy.

Your doctor will discuss the risks and benefits of taking this medicine whilst breast feeding.

5. You are allergic or intolerant to some sugars including lactose.

This medicine contains a small amount of lactose.

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

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 Fosinopril HCTZ may interfere with each other. These include:

- Antacids (medicines used to relieve heartburn, indigestion). These can reduce the absorption of Fosinopril. If you must take them, it is recommended that you take Fosinopril/ hydrochlorothiazide tablets at least 2 hours before or after taking antacids.
- Barbiturates (sedative drugs which may be used for treating sleeplessness or epilepsy)
- Medicines containing calcium salts
- Cholesterol lowering medicines (e.g. colestyramine or colestipol) - these should be taken one hour after, or four to six hours before, your Fosinopril HCTZ tablet.
- Cyclosporin or tacrolimus (used following organ transplants to lower the immune system)
- Corticosteroids (used to treat conditions such as rheumatism, arthritis, allergic conditions, certain skin diseases, asthma or certain blood disorders)
- Sleeping tablets

- Some medicines used during surgery or emergency situations, such as anaesthetics or muscle relaxants
- Lithium (used for depression or bipolar disorder)
- Medicines such as ephedrine, noradrenaline or adrenaline; drugs used by doctors to treat low blood pressure, heart failure, asthma or allergies.
- Medicines (including ones bought without prescription) for appetite control, asthma, colds, coughs, hayfever or sinus problems
- Medicines used to treat gout (e.g. allopurinol)
- Strong painkillers such as morphine
- Water tablets or diuretics (e.g. furosemide, amiloride)
- Other blood pressure lowering medicines
- Alcohol
- Pain relievers known as Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) (e.g. ibuprofen, aspirin) and COX-2 inhibitors (e.g. Celebrex). Taking a combination of. Taking these with Fosinopril/HCTZ may damage your kidneys.
- Potassium supplements or potassium containing salt substitutes
- Medicines for diabetes (tablets or insulin injection)

These medicines may be affected by Fosinopril HCTZ or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist can tell you if you are taking any of these medicines. They may also have more information on medicines to be careful with or avoid while taking Fosinopril HCTZ.

Other interactions not listed above may also occur.

How to take this medicine

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

They may be different to the information in this leaflet.

If you do not understand any written instructions, ask your doctor or pharmacist for help.

How much to take

Your doctor or pharmacist will tell you how many tablets you will need to take each day. This depends on your age, condition and whether or not you are taking any other medicines.

For adults the usual dose is one tablet taken once a day.

How to take it

Swallow the tablet whole with a full glass of water.

When to take it

Take it at about the same time each day.

Taking your medicine at the same time each day will have the best effect. It 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 two hours after your dose of Fosinopril HCTZ.

How long to take it for

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

It helps to control your condition but it does not cure it. Therefore you must take it every day.

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

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 medicine 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 (overdose)

Immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 for Australia) for advice, or go to the Accident and Emergency Department at the nearest hospital, if you think that you or anyone else may have taken too much Fosinopril HCTZ.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking Fosinopril HCTZ

Things you must do

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

Tell your doctor immediately if you become pregnant.

If you are about to have any blood or urine tests, tell your doctor that you are taking this medicine.

Go to your doctor regularly for a check-up.

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

Try not to miss any doses.

Take the medicine even when you feel well.

If you are about to be started on any new medicine, tell your doctor or pharmacist that you are taking Fosinopril HCTZ.

Tell your doctor if you have excessive vomiting or diarrhoea or you become dehydrated (light-headed, weak, dry mouth, thirsty, muscle pain or cramps, fast heart beat, passing less urine than normal).

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

If you do not drink enough water 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 Fosinopril HCTZ.

Having a general anaesthetic while taking this medicine may also cause your blood pressure to drop 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 this medicine especially if you are elderly.

If you have a pre-existing kidney problem you should follow up regularly with your doctor.

Things you must not do

Do not stop taking this medicine because you begin to feel better.

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

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

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

Stopping Fosinopril HCTZ without doctor's advice may worsen your condition. Your doctor will decide when you should stop taking it.

Things to be careful of

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

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

Make sure you know how you react to your medicine 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 of Fosinopril HCTZ

All medicines may have some unwanted side effects. Sometimes they are serious, but most of the time, they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

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

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
- Feeling sick (nausea) or being sick (vomiting)
- Constipation, diarrhoea (loose stools), pain in the stomach or upper stomach, indigestion, wind (flatulence), increased or decreased appetite, weight change, dry mouth, strange taste sensations, feeling thirsty, mouth ulcers, burping, heart burn, difficulty in swallowing
- Headache
- Tiredness, drowsiness, fatigue or weakness
- Dry cough
- Sore throat, blocked or runny nose, sinus problems, sneezing
- Aches and pains, cold or flu symptoms, flushing, weight loss
- Loss of memory, sleep disturbances, uncontrolled mood or mood swings, behavioural change, restlessness, shaking
- Pins and needles sensation, numbness, weakness of the extremities

- Blurred vision, visual disturbances, yellowish hue in vision (signs of a condition called xanthopsia, also called distortion of color vision)
- Vaginal bleeding
- Breast changes
- Prostate problems
- Sexual problems
- Bad breath
- Skin rash, acne, itching redness
- Increased blood pressure
- Hearing problems, ear infection, ringing in the ears
- Muscle cramps, spasm and pain, restricted mobility, joint pains
- Pain in the tendons
- Nosebleed
- Swollen glands
- Hoarse voice

The above list includes the more common side effects. Mostly, these are mild.

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

- Kidney problems (i.e. burning sensation or pain or problems urinating or urinating too much)
- Throat, nose, sinus or chest infection
- Severe dizziness
- 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
- Excessive sweating
- Sunburn following only a short exposure to the sun
- Feeling depressed, confused or hearing or seeing things that are not there
- Swollen ankles or lower legs
- Unusual bleeding or increased tendency to bleed, persistent sore throat and frequent infections, and/or anaemia
- Changes to your heart rhythm
- Pain and swelling of the stomach with no passage of wind or motions and being sick (vomiting) (signs of a condition called intestinal obstruction)

- Chest pain (see next section below also)
- Swelling of face, ankles or other parts of the body, with sudden increase or decrease in the amount of urine passed or have passed dark coloured urine
- Awareness of heart beat

These may be serious side effects. You may need medical attention. Most of these side effects are rare.

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

- Fainting
- Angina (feeling of tightness, heaviness, dull discomfort, or crushing pain that is felt behind the breastbone and may spread to the arms, neck and jaw.
- Myocardial Infarction (chest pain is more severe and prolonged than angina pain described above and may be associated with nausea (feeling sick), vomiting (being sick) and excessive sweating
- Sudden onset of a severe headache, dizziness, numbness/ weakness in the face, arm, or leg, especially on one side of the body, or altered speech and ability to understand, disturbed vision in one or both eyes, and loss of balance or coordination
- Symptoms of an allergic reaction which may include rashes, hives, itching, chest constriction, shortness of

breath or swelling of face, lips, tongue, hands/ feet, fainting, dizziness.

- Not urinating (passing water)
- Severe skin reactions with blisters, sores or ulceration
- Sudden onset of severe abdominal pain with or without nausea or vomiting
- Problems breathing
- Hepatitis or jaundice (symptoms may include nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching yellowing of the skin and eyes and dark coloured urine).

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

Whilst taking this medicine there may be different results from any blood or urine tests you may have. These may include the following:

- Abnormal liver function tests
- Increase in number of a type of cells in blood called eosinophils
- Abnormal deposits in urine
- Altered levels of electrolytes sodium and potassium

- Increased blood levels of uric acid/ glucose/ cholesterol/ triglycerides
- Abnormal kidney function tests

Your doctor will discuss with you what this means and how they will manage it.

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.

After taking this medicine

Storage

Keep your tablets in their original packaging until it is time to take them.

If you take the tablets out of their original packaging they may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25 degrees 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 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 this medicine or it has passed its expiry date, ask your pharmacist what to do with any medicine that is left over.

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

Product description

What APO-Fosinopril HCTZ looks like

APO-Fosinopril HCTZ 10/12.5 mg Tablets:

white to off-white, circular tablets, debossed with 'RC3' on one side and plain on the other side.

APO-Fosinopril HCTZ 20/12.5 mg Tablets:

white to off-white, flat beveled edged, circular tablets, debossed with 'FH1' on one side and plain on the other side.

Ingredients

Each tablet contains either 10 mg of Fosinopril sodium & 12.5 mg of Hydrochlorothiazide, OR 20 mg of Fosinopril sodium & 12.5 mg of Hydrochlorothiazide as the active ingredients.

It also contains the following inactive ingredients:

- Anhydrous Lactose
- Crospovidone
- Microcrystalline Cellulose
- Povidone
- Colloidal Anhydrous Silica
- Purified Talc

This medicine is gluten-free, sucrose-free, tartrazine-free and other azo dyes-free.

Australian Registration Numbers

APO-Fosinopril HCTZ 10/12.5 mg Tablets:

Blister packs of 30:

AUST R 151945.

APO-Fosinopril HCTZ 20/12.5 mg Tablets:

Blister packs of 30:

AUST R 151946.

Sponsor

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