

APO-Fosinopril HCTZ 20/12.5 Tablets

Contains the active ingredient fosinopril sodium and hydrochlorothiazide

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 APO-Fosinopril HCTZ 20/12.5. 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 HCTZ 20/12.5 Tablets. It contains the active ingredient fosinopril sodium and hydrochlorothiazide.

It is used to lower high blood pressure (hypertension).

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.

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.

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.

How it works

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.

There is no evidence that this medicine is addictive.

Use in children

The safety and effectiveness of fosinopril HCTZ in children have not been established.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You are pregnant**
Fosinopril HCTZ may affect your developing baby if you take it during pregnancy
- **Do not take fosinopril HCTZ if you are not producing any urine (anuric)**
- **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 APO-Fosinopril HCTZ 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**
- **You are hypersensitive to, or have had an allergic reaction to, fosinopril sodium or hydrochlorothiazide 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 hay fever-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. **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.**
3. You have or have had 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
 - systemic lupus erythematosus (SLE), scleroderma or other autoimmune diseases
 - impaired immune system either due to certain medical conditions or medications
 - diabetes or pre-diabetes
 - high levels of potassium in your blood (hyperkalaemia)
 - gout
 - have a problem passing urine
 - are going to have surgery (including dental surgery) involving a general anaesthetic, even if it is minor.
4. You plan to become pregnant. Do not take this medicine whilst pregnant.
5. You are currently breastfeeding or you plan to breast-feed. Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.
Both fosinopril and hydrochlorothiazide are detectable in breast milk.
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.

Some medicines may interact with fosinopril HCTZ. These include:

- diuretics, also known as fluid tablets (for example Lasix®, Urex®, Natrilix®, Moduretic®)
- other medicines used to treat high blood pressure
- lithium or lithium-containing medicine (for example Lithicarb®)
- potassium tablets (for example Span-K® or Slow-K®)
- potassium-containing salt substitutes (for example Pressor-K®)
- antacids
- alcoholic drinks
- sleeping tablets
- strong pain relieving medicines
- antidiabetic medicines (for example insulin)
- medicines or other tablets containing calcium
- antigout medicines
- 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
- 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 APO-Fosinopril HCTZ 20/12.5 and an anti-inflammatory medicine may damage your kidneys.

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 HCTZ.

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.

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

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.

Fosinopril HCTZ 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.

APO-Fosinopril HCTZ 20/12.5 tablet is not scored and must not be broken.

Since there is no lower dose (10/12.5 mg) of APO-Fosinopril HCTZ available, if a dose of 10/12.5 mg is required, an alternative product must be used.

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

How to take it

Swallow the tablet whole with a glass of water.

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.

How long to take it for

Fosinopril HCTZ helps to control your condition but does not cure it. Therefore you must take APO-Fosinopril HCTZ 20/12.5 every day. 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 breastfeeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

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 HCTZ or if your dose is increased.

- Make sure you drink enough water during exercise and hot weather while you are taking this medicine, especially if you sweat a lot, or your blood pressure may drop suddenly and you may dehydrate. If you experience any of the previous 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 APO-Fosinopril HCTZ 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 fosinopril HCTZ, especially if you are elderly.

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

Fosinopril HCTZ may cause dizziness, or light-headedness in some people. Make sure you know how you react to this 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.

Possible side effects

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

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 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)

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

These may be serious side effects and you may need medical attention:

- 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)

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 and you may need urgent medical attention or hospitalisation:

- fainting within a few hours of taking a dose of APO-FOSINOPRIL HCTZ 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.

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

Allergic reactions

If you think you are having an allergic reaction to fosinopril HCTZ, 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, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-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 it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Fosinopril HCTZ 20/12.5 tablets looks like

20/12.5 mg tablet: light orange coloured, round tablets with "FH" on one side.

APO-Fosinopril HCTZ 20/12.5 is available in blister packs of 30 tablets.

Ingredients

Each tablet contains 20 mg of fosinopril sodium and 12.5 mg of hydrochlorothiazide as the active ingredient.

It also contains the following inactive ingredients:

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

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

Australian Registration Numbers

APO-Fosinopril HCTZ 20/12.5 mg tablet (blister): AUST R 223503.

Sponsor

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