

FOSINOPRIL/HCT ACTAVIS 20/12.5

Fosinopril sodium and hydrochlorothiazide

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about FOSINOPRIL/HCT ACTAVIS 20/12.5.

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

All medicines have risks and benefits. Your doctor has weighed the risks of you taking FOSINOPRIL/HCT ACTAVIS 20/12.5 against the benefits they expect it will have for you.

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

Keep this leaflet with this medicine.

You may need to read it again.

What FOSINOPRIL/HCT ACTAVIS 20/12.5 is used for

FOSINOPRIL/HCT ACTAVIS 20/12.5 contain two medicines, fosinopril sodium and hydrochlorothiazide. Both medicines reduce blood pressure, but work in different ways.

Fosinopril sodium belongs to the class of medicines called Angiotensin Converting Enzyme (ACE) inhibitors that act on the heart and blood vessels.

Hydrochlorothiazide is a diuretic, it works by making your kidneys pass more water and salt.

Together fosinopril sodium and hydrochlorothiazide lower high blood pressure.

Your doctor will have prescribed FOSINOPRIL/HCT ACTAVIS 20/12.5 tablets for the following:

- Treatment of high blood pressure if treatment of high blood pressure is not satisfactory with fosinopril sodium alone.

Fosinopril sodium and hydrochlorothiazide tablets are not suitable for initial therapy of high blood pressure.

Your doctor may prescribe FOSINOPRIL/HCT ACTAVIS 20/12.5 for another reason. Ask your doctor if you have any questions about why FOSINOPRIL/HCT ACTAVIS 20/12.5 has been prescribed for you.

There is no evidence that FOSINOPRIL/HCT ACTAVIS 20/12.5 tablets are addictive.

FOSINOPRIL/HCT ACTAVIS 20/12.5 tablets are not recommended for use in children.

Before you take FOSINOPRIL/HCT ACTAVIS 20/12.5

When you must not take it

Do not take FOSINOPRIL/HCT ACTAVIS 20/12.5 if you are allergic to any of the following:

- Fosinopril sodium (or any other ACE inhibitors).
- Hydrochlorothiazide (or any other thiazides).
- Sulphonamides (possible cross-reaction)

- Any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching, shortness of breath, swelling of the tongue or face.

Do not take if any of the following applies to you:

- You have angioneurotic oedema that manifests with swelling of face, lips, hands/ feet, or breathing difficulties.
- You are not producing urine (anuric).
- You are pregnant, plan to become pregnant or are breast-feeding.

Do not take FOSINOPRIL/HCT ACTAVIS 20/12.5 after the expiry date printed on the pack.

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

Do not take FOSINOPRIL/HCT ACTAVIS 20/12.5 if the tablets do not look quite right.

Do not take FOSINOPRIL/HCT ACTAVIS 20/12.5 if the packaging is torn or shows signs of tampering.

Before you start to take it

Tell your doctor if you have any 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 or throat that may cause difficulty in swallowing or breathing.

Tell your doctor if you are pregnant, plan to become pregnant or are breast-feeding.

Taking FOSINOPRIL/HCT ACTAVIS 20/12.5 may harm your baby if you take it during pregnancy or whilst breast-feeding. This medicine may be absorbed into the womb or into breast milk. Your doctor will discuss the possible risks and benefits of using FOSINOPRIL/HCT ACTAVIS 20/12.5 during pregnancy or whilst breast-feeding.

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

- Systemic lupus erythematosus or scleroderma.
- Gout (build up of uric acid causing inflammation around your joints).
- Dehydration (eg. have had diarrhoea and/or vomiting recently).
- Diabetes (diabetes mellitus).
- Kidney and/or liver problems.
- Kidney transplant or are on haemodialysis.
- Very high blood pressure at the start of treatment.
- Heart problems.
- Renal artery stenosis.
- Abnormal levels of electrolytes (increased or decreased levels of sodium, potassium or chloride) in your blood.
- Treatment called LDL apheresis.

Tell your doctor if you are following a very low salt diet.

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

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

If you have not told your doctor about any of the above, tell them before you take FOSINOPRIL/HCT ACTAVIS 20/12.5.

Taking other medicines

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

Some medicines may interfere with the absorption or action of fosinopril sodium and hydrochlorothiazide:

- Alcohol, barbiturates or narcotics
- Antacids (to relieve heartburn, indigestion).
- Insulin and tablets used to treat diabetes
- Medicines used to treat gout (allopurinol).
- Medicines containing calcium salts.
- Cholesterol lowering medicines (eg. colestyramine or colestipol).
- Lithium (used for certain mental illnesses).
- Pain relievers known as Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) (eg. ibuprofen, aspirin).
- Diuretics, also known as fluid or water tablets.
- Potassium supplements or potassium containing salt substitutes.
- Medicines which lower your immune system, such as corticosteroids, cyclosporin or medicines used to treat cancer (including radiation therapy).
- General anaesthetics and drugs used during surgery.
- Other heart medications.
- Other blood pressure lowering medicines.

These medicines may be affected by fosinopril sodium and hydrochlorothiazide tablets, or may affect how well they work. You may need to use different amounts of your medicine or you may need to take different medicines.

Your doctor or pharmacist may have more information on medicines to be careful with or

avoid while taking FOSINOPRIL/HCT ACTAVIS 20/12.5.

How to take FOSINOPRIL/HCT ACTAVIS 20/12.5

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

They may differ from the information contained in this leaflet.

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

How much to take

Adults: The usual starting dose is one FOSINOPRIL/HCT ACTAVIS 20/12.5 tablet taken once daily.

FOSINOPRIL/HCT ACTAVIS 20/12.5 tablets are not recommended if you have severe kidney problems.

How to take it

Swallow the tablet whole with a glass of water.

FOSINOPRIL/HCT ACTAVIS 20/12.5 tablets may be taken with or without food.

When to take it

Take your FOSINOPRIL/HCT ACTAVIS 20/12.5 tablets at about the same time every day.

Taking your tablets at the same time will have the best effect. It will also help you to remember when to take the tablets.

If you need to take an antacid, take it at least 2 hours before or two hours after your dose of FOSINOPRIL/HCT ACTAVIS 20/12.5.

How long to take it

FOSINOPRIL/HCT ACTAVIS 20/12.5 helps to control your condition but does not cure it.

Therefore you must take FOSINOPRIL/HCT ACTAVIS 20/12.5 every day. Continue taking your medicine for as long as your doctor tells you.

Do not let yourself run out of medicine over the weekend or on 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, then go back to taking it as you would normally.

Do not double a dose to make up for the dose you have missed.

If you are not sure what to do, ask your doctor or pharmacist.

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

If you take too much (Overdose)

Immediately telephone your doctor, the Poisons Information Centre (13 11 26) or go to the Emergency department at your nearest hospital, if you think that you or anyone else has taken too many FOSINOPRIL/HCT ACTAVIS 20/12.5 tablets. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using FOSINOPRIL/HCT ACTAVIS 20/12.5

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking FOSINOPRIL/HCT ACTAVIS 20/12.5.

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

taking FOSINOPRIL/HCT ACTAVIS 20/12.5.

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

If you do not drink enough water while taking FOSINOPRIL/HCT ACTAVIS 20/12.5, 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 or diarrhoea while taking FOSINOPRIL/HCT ACTAVIS 20/12.5, tell your doctor.

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

If you feel light-headed or dizzy after taking your first dose of FOSINOPRIL/HCT ACTAVIS 20/12.5, tell your doctor.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking FOSINOPRIL/HCT ACTAVIS 20/12.5.

Your blood pressure may drop suddenly.

If you become pregnant while taking FOSINOPRIL/HCT ACTAVIS 20/12.5, tell your doctor immediately.

Tell your doctor if you are about to have any blood tests.
FOSINOPRIL/HCT ACTAVIS 20/12.5 may interfere with the results of some tests.

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

Visit your doctor regularly for check ups.

Your doctor may occasionally do a blood test to check your potassium levels and see how your kidneys are working.

Things you must not do

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

Do not use FOSINOPRIL/HCT ACTAVIS 20/12.5 to treat any other complaints unless your doctor tells you to.

Do not stop taking FOSINOPRIL/HCT ACTAVIS 20/12.5, or lower the dose, without first checking with your doctor.

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 will help your body get used to the change in position and blood pressure. Be careful the first time you take FOSINOPRIL/HCT ACTAVIS 20/12.5, especially if you are elderly.

Be careful driving or operating machinery until you know how FOSINOPRIL/HCT ACTAVIS 20/12.5 affects you.

As with other ACE inhibitor medicines, FOSINOPRIL/HCT ACTAVIS 20/12.5 may cause dizziness, or light-headedness in some people.

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 form of exercise 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 FOSINOPRIL/HCT ACTAVIS 20/12.5.

If you are over 65 years of age you may have an increased chance of getting side effects.

Ask your doctor or pharmacist to answer any questions you may have.

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

- Feeling light-headed, dizzy or faint
- Dry cough
- Headache
- Feeling sick (nausea) or vomiting
- Increase or decrease of appetite
- Stomach pain
- Diarrhoea
- Constipation
- Aching, tender or weak muscles not caused by exercise
- Muscle cramps
- Pain in the joints
- Unusual tiredness, weakness or fatigue, loss of memory, drowsiness.
- Difficulty sleeping or strange dreams

- Feelings of deep sadness and unworthiness (depression)
- Loss of sexual drive (loss of libido)
- Difficulty in getting or maintaining an erection (impotence)
- Ringing or buzzing in the ears (tinnitus)
- Hair loss or thinning
- Dry or itchy eyes
- Runny or blocked nose, or sneezing
- Facial pressure or pain (sinus pain)
- Dry mouth
- Taste disturbances or loss of taste
- Mouth or tongue ulcers
- Flushed or pale skin
- Fever, chills, weight loss
- Confusion or nervousness
- Indigestion, wind, increased thirst, burping, difficulty in swallowing.
- Vaginal bleeding.
- Urinary disturbances (associated with burning sensation or pain on passing urine).

These are the more common side effects of fosinopril sodium and hydrochlorothiazide. These side effects are usually mild and occur at the start of treatment.

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

- Unusual bleeding or increased tendency to bleed, persistent sore throat and frequent infections, and/or anaemia.
- Yellowing of skin and whites of eyes with decreased appetite.
- Irregular heart beat.
- Pain and distension of the belly with no passage of wind or motions and being sick (vomiting) (intestinal obstruction).
- Feeling faint and light-headed on change of posture.
- Chest pain and or chest infection.
- Bleeding from the nose.
- Swelling of face, ankles or other parts of the body, with sudden increase or decrease in the amount of urine passed or dark coloured urine.
- Sudden onset of severe abdominal pain with vomiting (pancreatitis).
- Awareness of heart beat.
- Angina (tightness, heaviness, dull discomfort, or crushing pain that is felt behind the breastbone and may spread to the arms, neck and jaw). Often brought on by exercise, eating, or stress; or may occur at rest. Angina occurs due to narrowing of blood vessels which supply the muscles of the heart, and the resulting failure to deliver enough oxygen for normal functioning of the heart.
- Myocardial Infarction (chest pain is more severe and prolonged than angina pain described above and may be associated with nausea, vomiting and excessive sweating (occurs due to a complete blockade in one or more of the blood vessels, which supply the muscles of the heart, and the resulting failure to deliver oxygen for normal functioning of the heart).
- 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 mental ability to understand, disturbed vision in one or both eyes, and loss of balance or coordination These symptoms may be short-lasting and reversible (“transient ischaemic attack”) or may continue (“stroke”).
- Allergic reaction (symptoms may include rashes, hives, itching, chest constriction, shortness of breath or swelling

of face, lips, tongue, hands/ feet, fainting, dizziness).

- Severe skin reactions with blisters, sores or ulceration.

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

All these side effects are very rare.

The following changes may be observed in your blood/ urine tests:

- 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.

Other side effects reported with the use of some ACE inhibitors are psychiatric reactions such as hallucinations (seeing, feeling, or hearing things that are not there.)

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

Tell your doctor if you notice anything else that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking FOSINOPRIL/HCT ACTAVIS 20/12.5

Storage

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

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

Keep your FOSINOPRIL/HCT ACTAVIS 20/12.5 tablets in a cool, dry place where it stays below 25°C.

Do not store it, or any other medicine, in the bathroom or near a sink. Do not leave it in the car on hot days.

Heat and dampness may destroy some medicines.

Keep this medicine where young 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 FOSINOPRIL/HCT ACTAVIS 20/12.5 or you find that they have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

Product description

What it looks like

FOSINOPRIL/HCT ACTAVIS 20/12.5 are light orange, round, tablets, marked with 'FH'.

Both strengths are available in blister packs of 30 tablets.

Ingredients

FOSINOPRIL/HCT ACTAVIS 20/12.5 contains the active ingredients: 20 mg of fosinopril sodium & 12.5 mg of hydrochlorothiazide

Inactive ingredients:

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

Supplier

Amneal Pharma Australia Pty Ltd
12 River Street
South Yarra VIC 3141
Australia

Australian Registration Numbers:

FOSINOPRIL/HCT ACTAVIS
20/12.5: AUST R 212128