Package leaflet: Information for the patient

Fosinopril Sodium Tablets 10mg and 20mg Tablets

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

1. What Fosinopril Sodium Tablets are and what they are used for

Each tablet contains the active ingredient fosinopril sodium which is used to treat high blood pressure (hypertension) and heart failure. Fosinopril Sodium Tablets belong to a group of medicines called ACE inhibitors and make it easier for the heart to pump blood around the body.

2. What you need to know before you take Fosinopril Sodium Tablets

Do not take Fosinopril Sodium Tablets:

- if you are allergic (hypersensitive) to fosinopril sodium, other ACE inhibitors or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to aliskiren.
- if you have become dehydrated (hyponatraemia) such as using them together may affect some blood counts
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Fosinopril Sodium Tablets:

- if you have kidney problems
- if you have liver problems
- if you are having dialysis
- if you are going to undergo treatment for hypersensitivity to bee or wasp stings (hyposensitisation)
- if you have problems with your immune system due to some diseases (eg scleroderma, lupus erythematosus), white blood cell counts will need to be monitored
- if you have high levels of sugar in your blood (diabetes)
- if you have narrowing of some blood vessels in the heart or cardiomyopathy (enlarged heart muscle)
- if you have become dehydrated from having recently suffered from vomiting or diarrhoea
- if you are on a low salt diet
- if you are Afro-Caribbean. If you are taking Fosinopril Sodium Tablets as the only treatment for your high blood pressure, you may have a reduced response to this medicine. This may mean that you may need a higher dose than usually recommended
- if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Fosinopril Sodium Tablets before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Fosinopril Sodium Tablets. Fosinopril sodium is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.
- if you are having dental treatment that you are being treated with fosinopril sodium, as there is a risk of your blood pressure sinking very low during the anaesthetic.

Other medicines and Fosinopril Sodium Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Sirolimus, everolimus and other medicines belonging to the class of mTOR inhibitors (used to avoid rejection of transplanted organs)

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (eg potassium) in your blood at regular intervals. See also information under the heading Do not take Fosinopril Sodium Tablets.

Tell your doctor or dentist before undergoing any surgery or dental treatment that you are being treated with fosinopril sodium, as there is a risk of your blood pressure sinking very low during the anaesthetic.

Other medicines and Fosinopril Sodium Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

It is especially important for your doctor to know if you are already being treated with any of the following medicines:

- other blood pressure lowering medicines including methyldopa, betablockers (eg atenolol), calcium antagonists (eg verapamil) or diuretics (water tablets) (eg furosemide) as it may lead to an increase in the blood pressure lowering effects
- medicines which are most often used to avoid rejection of transplanted organs (sirolimus, everolimus and other medicines belonging to the class of mTOR inhibitors). See section 'Warnings and precautions'.
- antacids (to relieve indigestion) stop the body absorbing fosinopril sodium. There should be at least 2 hours between taking the antacid and fosinopril sodium
- insulin and tablets used in diabetes, as fosinopril sodium may increase the effect of these especially during the first week of combination treatment
- lithium (used for manic depression), as fosinopril sodium may increase the concentration of lithium in the blood
- immunosuppressants (these reduce the body's natural defence system) such as azathioprine as using them together may affect some blood counts
- diuretic (water tablet) taken with fosinopril sodium may cause a reduction in blood pressure.

Your doctor may need to change your dose and/or to take other precautions:

- if you are taking an angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings Do not take Fosinopril Sodium Tablets and Warnings and precautions).

Pregnancy and breast-feeding

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Fosinopril Sodium Tablets before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Fosinopril Sodium Tablets. Fosinopril sodium is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. Fosinopril sodium is not recommended for mothers who are breast-feeding. Your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

Driving and using machines

If you experience dizziness, low blood pressure, light-headedness or vertigo (spinning sensation), do not drive or use machinery during treatment with fosinopril sodium.

Fosinopril Sodium Tablets contain lactose

If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine (see section 6 for further information).

Blood tests

Fosinopril sodium may interfere with the results of some blood tests. Tell your doctor that you are taking Fosinopril Sodium Tablets.

(continued overleaf)
3. How to take Fosinopril Sodium Tablets

Always take Fosinopril Sodium Tablets exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Swallow the tablets whole with at least ½ a glass of water in the morning with or without food. Do not chew or crush the tablets.

The recommended dose is:

Adults: The usual dose is 10mg once daily, up to a maximum of 40mg once daily.

Fosinopril Sodium Tablets may be taken alone or in combination with a diuretic (water tablet) or digoxin.

If you are already taking diuretics, your doctor may tell you to reduce the dose of the diuretic or to stop taking them for several days before beginning treatment with fosinopril sodium.

Occasionally some people start their treatment in hospital.

Use in children and adolescents under 18 years old. Not recommended.

If you take more Fosinopril Sodium Tablets than you should:

Symptoms associated with overdose may include severe hypotension and renal failure. Immediately contact your doctor, the nearest hospital casualty department or the centre for poison information for advice.

If you forget to take Fosinopril Sodium Tablets:

Do not take the missed dose, just carry on with the next one as normal. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

If you stop taking Fosinopril Sodium Tablets:

Do not stop taking Fosinopril Sodium Tablets unless your doctor advises you to do so. If you stop taking fosinopril sodium, your blood pressure may increase.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Fosinopril Sodium Tablets and contact your doctor immediately if you experience swelling of the face, lips, tongue and/or throat, rash, itching, breathlessness or difficulty swallowing (angioedema).

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Tell your doctor if you notice any of the following side effects or they get worse:

- Common (may affect up to 1 in 10 people):
  - infection of the upper respiratory tract (mouth, nose, throat or voice box), sore throat, runny nose, viral infections, bacterial infection of the lungs (pneumonia), laryngitis (inflammation of larynx (voice box) lining and vocal cords), sinusitis (inflammation of the sinuses), inflammation of the trachea and the bronchi, altered moods, sleep disorders, dizziness, headaches, pins and needles, eye disorders or problems with sight, pins and needles, eye disorders or problems with sight, quick or irregular heart beat, chest pain, feeling faint on standing up due to reduced blood pressure, low blood pressure, cough, sinus disorder, feeling or being sick, diarrhoea, stomach pain, indigestion, taste disturbance, pain in the muscles, tendons, ligaments and bone, problems urinating, fatigue, water retention (causing swelling in the body), weakness or loss of strength.

- Uncommon (may affect up to 1 in 100 people):
  - fainting, shock

- Not known (frequency cannot be estimated from the available data): changes in types and number of blood cells you may experience sore throat, recurring infections, nose bleeds, increased bruising), lack of appetite, appetite disorders, weight fluctuation, gout, raised levels of potassium in the blood, depression, abnormal behaviour, confusion, stroke, tremor, memory problems, problems with balance, sleepiness or drowsiness, ear ache, tinnitus (ringing in the ear), vertigo (spinning sensation), heart attack, problems with heart rhythm or heart rate, flushing, high blood pressure or severe high blood pressure, bleeding, narrowing of the arteries in the legs, difficulty breathing or wheezing, congestion of the lungs, disorder of the voice (hoarse or weak voice), nosebleeds, inflammation of the sinuses, chest pain (not related to the heart), inflammation of the pancreas, swollen tongue, difficulty swallowing, constipation, dry mouth, flatulence, inflammation of the liver (causing yellowing of the skin or eyes or tiredness, pain in abdomen, joint or muscles), excessive sweating, bruising, itching, dermatitis (skin problems/inflammation of the skin), skin rash that may be itchy (caused by an allergic reaction, pale or red irregular raised patches on the skin (hives)), weakness of the muscles, arthritis (pain and swelling of the joints), kidney failure, problems with sexual function, abnormality or disease of the prostate gland, swelling of the soft tissue, fever with pain, increase in weight, abnormal liver function tests, bloating of the stomach, mouth problems.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Fosinopril Sodium Tablets

Keep this medicine out of the sight and reach of children. Do not store above 25°C. Keep in the original packaging. Keep the container tightly closed to protect from moisture.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or house hold waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Fosinopril Sodium Tablets contain:

- The active substance is fosinopril sodium. Each tablet contains either 10mg or 20mg fosinopril sodium.
- The other ingredients are lactose monohydrate, modified starch, crosscarmellose sodium (E466), microcrystalline cellulose (E467), glycerol dibehenate and purified water.
- The sodium content is 0.67mg per 10mg tablet and 1.06mg per 20mg tablet.

What Fosinopril Sodium Tablets look like and contents of the pack:

Fosinopril Sodium Tablets are white to off white, round, flat, uncoated tablets.

The 10mg strength tablet is marked ‘FL 10’. The 20mg strength tablet is marked ‘FL 20’.

Each pack contains 30 tablets.

PL holder:

Manx Healthcare Ltd, Taylor Group House, Wedgnock Lane, Warwick, CV34 5YA

PL 14251/0037 Fosinopril Sodium 10mg Tablets
PL 14251/0038 Fosinopril Sodium 20mg Tablets

Procured from within the EU

Manufacturer:

Actavis hf, Reykjavikurvegur 78, IS-220 Hafnarfjordur, Iceland

To request a copy of this leaflet in large print, audio or Braille, please call 01926 482511.

This leaflet was last revised in January 2018