

Fosinopril Sodium 10mg Tablets

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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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 or a member of your family have **previously had swelling** of the legs, arms, face, mucous membranes or tongue and/or throat (angioedema), with or without ACE inhibitor treatment
- if you have **narrowing of the blood vessels** in one or both **kidneys**
- if you are in **shock** due to heart problems (cardiogenic shock)
- if you are more than 3 months **pregnant** (it is also better to avoid fosinopril sodium in early pregnancy – see 'Pregnancy and breast-feeding' section)
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing **aliskiren**
- if you have taken or are currently taking **sacubitril/valsartan**, a medicine used to treat a type of long-term (chronic) heart failure in adults, as the risk of angioedema (rapid swelling under the skin in an area such as the throat) is increased.

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 (e.g. 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**. Fosinopril sodium is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as they may cause serious harm to your baby if used at that stage (see pregnancy section)
- if you are **taking** any of the following **medicines used to treat high blood pressure**:
 - an angiotensin II receptor blocker (ARBs) (also known as sartans – for example valsartan, telmesartan, irbesartan), in particular if you have diabetes-related kidney problems
 - aliskiren

- if you are taking any of the following medicines, the risk of **angioedema** may be increased:
 - **racecadotril**, a medicine used to treat diarrhoea
 - medicines used to **prevent organ transplant rejection** and for cancer (e.g. temsirolimus, sirolimus, everolimus)
 - **vildagliptin**, a medicine used to treat diabetes.

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. 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.

Children and adolescents

Do not give to children or adolescents under 18 years old.

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 methyl dopa, betablockers (e.g. atenolol), calcium antagonists (e.g. verapamil) or diuretics (water tablets) (e.g. 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"
- **potassium** supplements (including salt substitutes), potassium-sparing diuretics and other medicines that can increase the amount of potassium in your blood (e.g. trimethoprim and co-trimoxazole for infections caused by bacteria; ciclosporin, an immunosuppressant medicine used to prevent organ transplant rejection; and heparin, a medicine used to thin blood to prevent clots)
- **painkillers** and anti-inflammatory medicines of the NSAID type (e.g. aspirin or indometacin) as they can reduce the effect of fosinopril sodium
- **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, cytostatics as using them together may affect some blood counts
- **tricyclic antidepressants** e.g. amitriptyline or dosulepin, or **antipsychotics** (used for psychiatric problems) e.g. flupenthixol
- medicines known as **sympathomimetics** e.g. salbutamol, ephedrine and some medicines for colds, coughs or flu symptoms which may contain these ingredients
- **systemic corticosteroids** e.g. prednisone
- **allopurinol** (used to treat gout)
- **glyceryl trinitrate and other nitrates** used to treat angina (chest pain)
- **procainamide** (used to treat abnormal heart rhythms).

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').

Fosinopril Sodium Tablets with food and drink

DO NOT drink alcohol whilst being treated with Fosinopril Sodium Tablets.

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, and 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.

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 and Elderly: 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 digitalis (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.

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:

Common (may affect up to 1 in 10 people):

- swelling of the face, lips, tongue and/or throat, rash, itching, breathlessness or difficulty swallowing (angioedema), upper or lower chest infection
- changes in heart rate or chest pain related to the heart
- yellowing of the skin and eyes (increase in bilirubin).

Uncommon (may affect up to 1 in 100 people):

- weakness, nausea, tingling caused by high blood potassium levels
- blockages/narrowing of blood vessels in the brain, heart attack or stroke, changes in heart rhythm, shock
- kidney failure
- depression
- sudden death.

Rare (may affect up to 1 in 1,000 people):

- blood disorders which may be characterised by fever or chills, sore throat, ulcers in your mouth or throat, low blood count causing unusual tiredness or weakness, unusual bleeding or unexplained bruising
- breathlessness, pneumonia, congestion in the lungs
- inflammation of the pancreas, hepatitis (inflammation of the liver).

Very rare (may affect up to 1 in 10,000 people):

- severe reduction in number of white blood cells making infections more likely
- inflammation and swelling of the bowel
- liver failure.

Not known (frequency cannot be estimated from the available data):

- difficulty breathing
- severe increase in blood pressure.

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):

- viral infection
- altered mood, sleepiness or sleep disturbances, dizziness, headache, pins and needles
- eye disorder, visual disturbances
- fast or hard heart rate
- low blood pressure which may cause fainting or dizziness when standing
- cough, runny or itchy nose
- feeling or being sick, diarrhoea, abdominal pain, indigestion
- rash, swelling, dermatitis
- bone, joint or muscle pain
- problems urinating

- sexual problems
- tiredness, chest pain not related to the heart, swelling of the hands and feet, lack of energy, weakness
- increase in LDH or transaminases seen in blood tests.

Uncommon (may affect up to 1 in 100 people):

- abnormal blood test results, increases in blood urea, serum creatinine seen in blood tests
- decreased appetite, constipation, dry mouth, flatulence, weight increase, taste disturbances
- fainting, drowsiness, shaking, sleep disturbances, confusion
- ear pain, ringing in the ears, a sensation that your surroundings are spinning either up and down or from side to side
- collapse of the blood circulation with low blood pressure
- high blood pressure
- stuffy nose or congestion, sinusitis (inflammation of the sinus)
- excessive sweating, itchy rash, red, raised, itchy rash
- protein in the urine
- fever, swelling of the arms and legs, back pain, gout.

Rare (may affect up to 1 in 1,000 people):

- problems in the ability to select words in which to speak, read or write, memory problems, disorientation
- flushing, nose bleeds, peripheral vascular disease (disease of arteries)
- swollen tongue or mouth sores, abdominal swelling, difficulty swallowing
- bleeding under the skin
- arthritis
- prostate problems
- weakness in limbs
- low levels of salt in the blood.

Not known (frequency cannot be estimated from the available data):

- laryngitis (inflammation of larynx (voice box) lining and vocal cords)
- changes in appetite disorder, weight fluctuation
- abnormal behaviour
- balance problems, difficulty speaking
- sudden, intense or sharp chest pain whilst breathing
- abnormal liver function test
- pain, high temperature.

A disorder which may include fever, vasculitis (inflammation of blood vessels), muscle pain, joint pain/arthritis, blood disorders, rash, sensitivity to light or other skin problems has been reported.

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 Fosinopril Sodium Tablets above 25°C.

Do not transfer to another container.

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 household 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 10mg of fosinopril sodium.
- The other ingredients are lactose monohydrate, croscarmellose sodium, pregelatinised starch (maize), microcrystalline cellulose, glycerol dibehenate and magnesium stearate.
- The sodium content is 0.67mg per 10mg tablet.

What Fosinopril Sodium Tablets look like and contents of the pack

Fosinopril Sodium 10mg Tablets are white to off-white, circular, flat, uncoated 8mm tablets marked 'FL 10'.

Each pack contains 28 tablets.

Marketing Authorisation Holder

Accord, Barnstaple, EX32 8NS, UK

Manufacturer

Balkanpharma-Dupnitsa AD, 3 Samokovsko Shosse Str., Dupnitsa 2600, Bulgaria

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If you would like a leaflet with larger text, please contact 01271 385257.