Fosinopril Sodium 20mg 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 or pharmacist. 

• 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 "Side effects".

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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.

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 a member of a family previously had swollen legs, the 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').

• If you have diabetes or impaired kidney function and you are treated with any of the following medicines:

• aliskiren (used to treat abnormal heart rhythms).

• medicines which are most often used to treat high blood pressure (e.g. diuretics, beta blockers, calcium antagonists, angiotensin II receptor blockers (ARBs) (also known as sartans – for example, losartan, valsartan and irbesartan)).

• medicines which contain these ingredients (used to treat abnormal heart rhythms). See section "Warnings and precautions".

• 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 aspirin/substitutes, a medicine used to treat platelet (blood cell) activity in adults, as the risk of angioedema (swollen skin under the skin) is increased.

Warnings and precautions

Tell your doctor or pharmacist if you are going to breast-feed, especially if your baby is newborn, or was breast-feeding. Fosinopril sodium is not recommended for mothers who are breast-feeding.

Breast-feeding

Breast-feeding mothers: You must tell your doctor if you think you are (or might become) pregnant. 

If you are pregnant and will advise you to take another medicine instead of 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 has been prematurely.
Driving and using machines
If you experience dizziness, low blood pressure, light-headedness or vertigo (spinning sensations) 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 4 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.

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 1 glass of water in the morning or without food. Do not chew or crush the tablets.
The recommended dose
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 take 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.

Possible side effects
Like all medicines, this medicine can cause side effects, although not everyone 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 or throat, rash, itching, breathlessness or difficulty swallowing (angioedema), upper or lower chest infection
• severe heart rate or chest pain related to the heart
• low blood pressure

Uncertain (may affect up to 1 in 100 people):
• weakness, nausea, tingling caused by high blood potassium levels
• blockages/hardening of blood vessels in the brain, heart attack or stroke, changes in heart rhythm, shock
• sudden kidney failure

Rare (may affect up to 1 in 1000 people):
• blood disorders which may be characterised by fever or chills, sore throat, ulcers in mouth or throat, low blood count causing unusual tiredness or weakness, unusual bleeding or unplanned bruising
• breathlessness, pneumonia, congestion in lungs
• inflammation of the pancreas, hepatitis (inflammation of the liver)
• severe reactions in 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
• fever

Netunknown (frequency cannot be estimated from the available data):
• difficulty breathing
• swelling 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):
• nasal infection
• altered mood, sleepiness or sleep disturbances, dizziness, headache, pins and needles
• eye disorders or vision disturbances
• fast or hot heart rate
• low blood pressure which may cause fainting or dizziness when standing
• cough or itchy nose
• feeling or being sick, diarrhoea, abdominal pain, indigestion
• rash, swelling, dermatitis

• bone, joint or muscle pain
• problems swallowing
• unusual problems
• skin rash not related to the heart, swelling of the hands and feet, lack of energy, weakness
• increase in 24-hour renin measurements seen in blood tests.
Uncertain (may affect up to 1 in 100 people):
• abnormal blood test results, increased in blood area, serum creatinine seen in blood tests
• blood disorders which may be characterised by fever or chills, sore throat, ulcers in mouth or throat, low blood count causing unusual tiredness or weakness, unusual bleeding or unplanned bruising
• fever

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 bleed, peripheral vascular disease (arteries)
• sudden 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):
• anxiety (inflation of irregular voice (breath) and vocal cords)
• changes in appetite disorder, weight fluctuation
• abnormal behaviour
• balance problems, difficulty swallowing
• rashes, irritation of skin, heat pain whilst breathing
• abnormal liver function test
• pain, high temperature
• a disorder which may include fever, varicella (inflammation of blood vessels), measles, purpura, 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.

How to store Fosinopril Sodium Tablets
Keep the medicine out of the sight of 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.

Contents of the pack and other information
What Fosinopril Sodium Tablets contain
The active substance is fosinopril sodium. Each tablet contains 20mg of fosinopril sodium.
The other ingredients are lactose monohydrate, croscarmellose sodium, pregelatinised starch ( maize), magnesium stearate, colloidal silicon dioxide, glycerol dibehenate and magnesium stearate.
The sodium content is 10mg per 20mg tablet.
What Fosinopril Sodium Tablets look like and contents of the pack
Fosinopril Sodium Tablets are white to off-white, round, uncoated tablets. Each pack contains 20 tablets.
Marketing Authorisation Holder
Accord, Barnstaple, EX32 8NS, UK
Manufacturer
Slovenská farmácia Opičinská 4K, 3 Samokovská Stree, Dunajská Streda, 8000, Bulgaria
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Approved for print dates:

Min Body Text Size: 9pt

Dimensions: 190 x 130

Colours: 1. Black

Non Printing Colours:

1. Red

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