Fosinopril Sodium 10 mg Tablets
Fosinopril Sodium 20 mg Tablets

Fosinopril sodium

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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet
1. What Fosinopril is and what is it used for.
2. What you need to know before you take Fosinopril.
3. How to take Fosinopril.
4. Possible side effects.
5. How to store Fosinopril.
6. Contents of the pack and other information.

1. What Fosinopril is and what is it used for

Fosinopril belongs to the class of medicines called Angiotensin Converting Enzyme (ACE) inhibitors that act on the heart and blood vessels. You may have been given Fosinopril to:

- lower your blood pressure if it is too high (a condition called hypertension)
- help your heart pump blood around your body if you have a condition known as heart failure and are also being treated with diuretics (medicines which help to remove excess fluid from the body).

2. What you need to know before you take Fosinopril

Do not take Fosinopril:

- if you are allergic to fosinopril or any other ACE inhibitor, or any of the other ingredients of this medicine (listed in section 6). An allergic reaction may include rash, itching, swelling of face, lips, tongue, hands and feet, or breathing difficulties.
- if you know you have, or know that someone in your close family has, a condition called angioneurotic oedema where the face, lips, hands or feet swell up, or you have breathing difficulties. If you develop these symptoms during treatment you should stop taking Fosinopril.
• if you are more than 3 months pregnant (it is also better to avoid Fosinopril in early pregnancy – see Pregnancy section.)

• if you have a condition known as renal artery stenosis (narrowing of the artery supplying blood to the kidney)

• if you have recently had a heart attack, or if your heart is unable to maintain an adequate blood flow around the body due to a serious, sudden, decrease in blood pressure (cardiogenic shock).

• 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 or pharmacist before taking Fosinopril

• if you are dehydrated, for example due to • treatment with medicines such as diuretics • a dietary restriction of salt • vomiting or diarrhoea. You may be more likely to suffer from a large drop in blood pressure when you first start taking the tablets and may feel faint or light headed

• if you have kidney problems, or are undergoing dialysis treatment

• if you have liver problems

• if you are undergoing a desensitisation treatment to insect stings, such as that to bees or wasps

• if you have your blood fat (lipid) levels controlled using a method called LDL apheresis

• if you have diabetes

• if you suffer from a collagen vascular disease e.g. scleroderma, systemic lupus erythematosus (also known as lupus or SLE, an allergic condition causing joint pain, skin rashes and fever)

• if you suffer from heart valve disease, such as a narrowing of the aortic or mitral valve in the heart, or an enlarged heart

• if you are of African or Caribbean descent. This medicine may not be effective for you

• if you are (or might become) pregnant. Fosinopril tablets are not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it 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, telmisartan, 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.
  - 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 (e.g. potassium) in your blood at regular intervals.
See also information under the heading “Do not take Fosinopril”

If you are taking Fosinopril for heart failure. Your doctor may want to check your blood pressure or how your kidneys are working regularly when you first start taking the tablets or when the amount of Fosinopril or other medicines, such as diuretics (medicines which help to remove excess fluid from the body), you take changes.

Other medicines and Fosinopril

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription, or the following:

- potassium supplements (including salt substitutes), potassium sparing diuretics and other medicines that may increase levels 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.)
- antacids (to relieve indigestion). Do not take antacids within 2 hours of your Fosinopril
- pain killers called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) used to treat pain and inflammation e.g. aspirin, ibuprofen, naproxen, indometacin
- lithium (used to treat certain mental illnesses)
- other medicines to treat high blood pressure e.g. methyldopa, atenolol, verapamil or diltiazem
- immunosuppressants (used to suppress the immune system) such as corticosteroids (used to treat arthritis and allergic reactions), ciclosporin (used to prevent rejection of organ transplants)
- 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”
- digoxin (a heart medicine) as Fosinopril may interact with certain lab tests used to monitor this medicine.

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” and “Warnings and precautions”).

If you are going to have an operation or need an anaesthetic tell your doctor or dentist that you are taking Fosinopril. ACE inhibitors can cause your blood pressure to fall (hypotension) during surgery or anaesthesia.

If you are on dialysis, serious allergic reactions may occur if your machine has components made of high flux membranes and dextran sulfate. This medicine should not be used in such cases.

If you are having a test for the function of your parathyroid (small glands in the neck which produce the parathyroid hormone) tell the doctor that you are taking Fosinopril.

Pregnancy
If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Your doctor will normally advise you to stop taking Fosinopril before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Fosinopril. Fosinopril tablets are 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**

If you are breast-feeding or about to start breast-feeding, ask your doctor or pharmacist for advice before taking this medicine. Fosinopril tablets are 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**

Do not drive or operate machinery if you feel dizzy, faint or tired while taking this medicine.

### 3. How to take Fosinopril

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- Swallow the tablets with a glass of water
- You can take Fosinopril with or without food
- To help you remember to take your medicine, try to get into the habit of taking it at the same time each day.
- At the start of treatment your doctor may monitor your condition closely, take blood tests, check your kidney function and monitor the level of salts in your blood from time to time. This will happen more often if you have a kidney problems or a collagen vascular disease.

The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

**Adults, including older people**

**To treat high blood pressure:** The recommended starting dose is 10 mg once a day. Your doctor may increase this after 4 weeks, to a dose which best controls your blood pressure. The recommended daily dose needed is between 10 mg and 40 mg taken as a single dose. If you are already taking a diuretic ("water" tablet) your doctor may either monitor you very closely or stop the diuretic treatment for a few days before starting Fosinopril.

**To treat heart failure:** You will also be taking other medicine for your condition, such as a diuretic ("water" tablet). The recommended starting dose is 10 mg once a day. Your doctor will slowly increase this, if necessary, up to 40 mg once a day. At the start of treatment your doctor will monitor your condition closely. In some cases your doctor may wish to take the precaution of placing you in hospital just for the start of therapy.
People with liver or kidney problems - If you have liver or kidney problems, you may be more sensitive to the effects of Fosinopril. Your doctor will give you the lowest dose possible to control your condition.

Children and adolescents
Children and adolescents who weigh less than 50 kg in weight should not take Fosinopril.

If you take more Fosinopril than you should - Contact your doctor or nearest hospital emergency department immediately. Take the container and any remaining tablets with you. Symptoms of overdose include a severe decrease in blood pressure, which may make you feel dizzy or faint, a feeling of confusion or loss of consciousness, a slow heartbeat, and serious kidney problems.

If you forget to take Fosinopril - Take your next dose when it is due. Do not take a double dose to make up for a forgotten dose.

If you stop taking Fosinopril - Do not stop taking Fosinopril without speaking to your doctor first. If you stop taking the medicine your symptoms may return. You should check with your doctor or pharmacist if you are not sure.

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

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

If any of the following happen, stop taking Fosinopril and tell your doctor immediately or go to your nearest hospital emergency department:

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

- if you begin to itch, get short of breath or wheezy, and develop swelling of the face, hands, feet, mouth, throat or eyes. These are symptoms of an allergic reaction
- a potentially serious decrease of blood pressure, which if untreated, may lead to collapse, a coma and death

Rare (may affect up to 1 in 1000 people):

- inflammation of the pancreas which causes severe pain in the abdomen and back

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

- yellowing of your skin or whites of your eyes or an increase of the liver markers in your blood (these may be signs of a liver problem)
- little or no urine being produced, cloudy urine or blood in the urine (these may be signs of kidney problems)
- sudden collapse, numbness or weakness in the arms or leg, headache, dizziness and confusion, disturbances in vision, difficulty swallowing, slurred or loss of speech (these may be signs of a stroke caused by a clot or bleed affecting blood supply to parts of the brain)
• sudden chest pain which may spread to the neck and shoulders and cause you to feel clammy and short of breath (these may be signs of a heart attack or other problems with your heart)
• a very large increase in blood pressure that can cause organs of the body to not work effectively (you may have a severe headache, be sick)
• an increase in the number of infections you get such as fever, severe chills, sore throat or mouth ulcers (this may be a sign of changes in the number of white blood cells in your blood)
• chest infections, including pneumonia which is a serious chest infection (if you have pneumonia you may also have a fever, chills, shortness of breath and a cough which may produce phlegm or occasionally blood), fluid on the lungs, pain when breathing in and out

Other side effects include:

Common (may affect up to 1 in 10 people):
• low blood pressure, especially when moving from sitting or lying down to standing (you may feel faint or light headed)
• an irregular or fast heartbeat, a sensation of thumping in the chest (these may be signs of a problem with your heart)
• swelling or infection of the sinus, itchy, runny nose
• a dry persistent cough, which does not produce phlegm on the chest
• swelling or infection of the throat, which may cause some difficulty in swallowing or you to lose your voice
• taste changes, feeling sick, being sick, indigestion or heartburn, pain and bloating in the stomach and abdomen, diarrhoea
• tingling or numbness in the fingers and toes, muscle, joint or bone pain
• itchy red skin, rashes
• difficulty in passing urine, difficulties during sexual activity
• changes in mood, problems sleeping, feeling unusually tired, a general feeling of weakness or loss of strength

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

Not known (frequency cannot be estimated from the available data):
• an increase in blood pressure, reduced blood flow in the arms and legs (which may cause pain on walking)
• problems balancing, shaking, loss of memory, feeling depressed, feeling very sleepy, unusual behaviour
• swelling of glands (such as those in the armpits), tongue or joints, excessive sweating, pinkish itchy swellings on the skin (known as hives or nettle rash)
• bleeding or bruising, nose bleeds
• painful, swollen joints caused by uric acid crystals (gout), pain
• changes in appetite, weight gain or fluctuations of weight, dry mouth, passing wind, constipation, prostate problems in men
• a sensation of ringing in the ear, pain in the ear
• flushing

• laboratory tests may show: • a small decrease of the substance (haemoglobin) or red blood cells that carry oxygen in your blood • a small increase of your blood urea level • an increase of your blood potassium level • an increase in blood urea nitrogen (BUN) • an increase of your blood creatinine level.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. 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

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Fosinopril

Keep this medicine out of the sight and reach of children.

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

Do not store above 25°C. Store in the original package in order to protect from moisture. Keep the container tightly closed.

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

6. Contents of the pack and other information

What Fosinopril tablets contain

The active substance is fosinopril sodium. Each tablet contains either 10 mg or 20 mg fosinopril sodium.

The other ingredients are maize starch, pregelatinised, cellulose, microcrystalline, sodium starch glycolate, hydroxypropylcellulose, crospovidone, and glycerol dibehenate.

What Fosinopril tablets looks like and contents of the pack

Your medicine comes as a white to off-white tablet.

The 10 mg tablets are rectangular shaped with 'G' scoreline 'G' on one side and 'FS' scoreline '10' on the other side.

The 20 mg tablets are capsule shaped with 'G' scoreline 'G' on one side and 'FS' scoreline '20' on the other side.
Fosinopril is available in blister packs of 10, 14, 20, 28, 30, 50, 60, 84, 90, 100 and 250 tablets or plastic containers (with desiccant and an optional filler) of 30, 60 and 250 tablets. Not all pack sizes may be marketed.

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