Fosinopril sodium
P15XXXXX

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Package leaflet: Information for the user

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

What is in this leaflet:

1. What Fosinopril sodium is and what it is used for

Fosinopril belongs to a group of medicines known as ACE (angiotensin converting enzyme) - inhibitors. Fosinopril binds to the ACE in the body, thereby inhibiting the formation of angiotensin II, a substance which raises the blood pressure. Angiotensin II also has a vasoconstricting effect which narrows the blood vessels. By inhibiting this substance, there is a decrease in pressure inside the blood vessels and heart function can be improved.

Fosinopril sodium is prescribed if you have high blood pressure, or if the heart is not working sufficiently, this is known as “heart failure”.

2. What you need to know before you take Fosinopril sodium

Do not take Fosinopril sodium
- If you are allergic to fosinopril sodium or any of the other ingredients of this medicine (listed in section 6) or to other angiotensin-converting enzyme (ACE) inhibitors.
- If you have ever experienced hypersensitivity reactions in the past, such as skin reactions and sudden fluid accumulation in the skin and mucous membranes (e.g. throat or tongue), breathing difficulties and / or itching and skin rash (known as angioedema) after taking an ACE inhibitor, or without any apparent cause, or if there is a history of such reactions in your family.
- In cases of hereditary angioedema or angioedema of unknown cause.
- If you are more than three months pregnant (it is also better to avoid Fosinopril sodium in early pregnancy - see Pregnancy 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
The starting dose of 10 mg has not been studied in patients over 75 years of age receiving treatment for heart failure, or in patients with severe NYHA class IV heart failure.
A severe drop in blood pressure or hyperkalaemia (too much potassium in the blood) may occur at the start of treatment with 10 mg fosinopril in:
- patients with severe heart failure (NYHA class IV)
- the elderly
- patients with kidney dysfunction receiving treatment for heart failure
- patients with high blood pressure receiving treatment with water tablets (diuretics)

You must tell you doctor if you think you are (or might become) pregnant. Fosinopril is 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).

Talk to your doctor or pharmacist before taking Fosinopril sodium
- You may experience an excessive drop in blood pressure. Although rare, this can occur after the first dose, if you are dehydrated (e.g. due to vomiting, a low-salt diet, dialysis, diarrhea, or therapy with diuretics (water tablets)) or if you have a certain type of high blood pressure (known as severe renin-dependent hypertension). An excessive drop in blood pressure may also occur if you suffer from heart failure. This risk is increased if you have severe heart failure, whereby you are using high dose loop diuretics (a certain group of water tablets), your blood sodium levels are too low (hyponatremia) or your kidney function is reduced. If you are at increased risk of experiencing an excessive drop in blood pressure, you should be closely monitored at the start of treatment and whenever there is change in dosage. This also applies to you if you have an ischaemic heart failure (a certain type of heart disease) or disorders affecting the blood vessels in your brain (cerebrovascular disorders). In this case, treatment should be administered with particular caution, as any massive drop in blood pressure could lead to a heart attack or brain haemorrhage.
- If your blood pressure should fall too low. In this event, you should be placed in a lying position and, if necessary, given an infusion with physiological saline. This does not mean that your treatment will have to be stopped. Once your blood volume and blood pressure have been restored, treatment may be resumed, possibly at a lower dose, or continued as before.
- If you suffer from heart failure and your blood pressure is low or normal. A further reduction in blood pressure may occur. If this persists, it may become necessary to reduce the dose or stop your treatment.
- If you have aortic stenosis (narrowing of the body’s major artery), mitral valve stenosis (a stricture in the heart) or hypertrophic cardiomyopathy (thickening of the heart muscle wall). In this case, you should use fosinopril with caution.
- If you have poor kidney function, there is no need to adjust the starting dosage. In this case, potassium and creatinine levels in your blood should be regularly monitored.
- If you suffer from heart failure. A sharp drop in blood pressure caused by use of fosinopril may lead to poor kidney function and even acute kidney failure (which is generally temporary).
- If you have renal artery stenosis (narrowing of one or both arteries to your kidneys), fosinopril can cause an increase in certain substances in the blood (i.e. so-called urea and creatinine levels may rise), particularly if you suffer from poor kidney function.
- If you have renovascular hypertension (high blood pressure due to narrowing of the artery leading to your kidneys), you are at increased risk of experiencing a severe drop in blood pressure and poor kidney function. In this case, treatment should therefore be administered under strict medical surveillance with low doses and cautious dose increases. In addition, any treatment with water tablets (diuretics) should be stopped. Kidney function should also be monitored during the first few weeks of treatment.
- Because, in some patients with high blood pressure without renovascular (kidney) disease, fosinopril can cause an increase in certain substances in the blood (i.e. so-called urea and creatinine levels may rise). Such increases are generally minor and temporary, particularly if fosinopril is given at the same time as a diuretic (water tablet). If this occurs, treatment should be stopped. If necessary, treatment can be resumed later at a reduced dosage. The risk of experiencing such side effects is greater in patients with an existing kidney disorder.
- In patients with pre-existing kidney dysfunction, proteinuria (excretion of protein in the urine) may occur in rare cases. If this exceeds 1 g/day, fosinopril may only be used after careful consideration of the benefits and risks and with regular monitoring of laboratory test results.
- If you experience hypersensitivity reactions, such as skin reactions and sudden fluid accumulation in the skin and mucous membranes (e.g. in the face, arms and/or legs, lips, tongue, throat or voice box), breathing difficulties and/or itching and skin rash (so-called angioedema). You should stop using fosinopril at once, appropriate measures should be taken and you should be kept under close observation until the symptoms completely disappear. If swelling affects the tongue, throat or voice box, the airways may become blocked, especially if you have ever had airway surgery. In such cases, immediate first-aid therapy should be given. If you have ever experienced angioedema during use of any other medicines, you may now be at increased risk of experiencing angioedema again.
- If you are of Afro-Caribbean origin. This is because fosinopril may be less effective in some Afro-Caribbean patients. In addition, some Afro-Caribbean patients may be more prone to developing severe hypersensitivity reactions (angioedema, see previous warning) than non-Afro-Caribbean patients.
- If you are receiving dialysis with high-flux membranes (e.g. AN 69). In this case, severe hypersensitivity reactions (anaphylactic reactions) may occur. For this reason, consideration should be given to using a different type of dialysis membrane or a different class of antihypertensive (blood pressure-lowering) agents.
- During LDL apheresis (a certain type of treatment for removing cholesterol from the blood) with dextran sulphate. This is because life-threatening hypersensitivity reactions may occur in rare cases. These can be avoided by temporarily suspending treatment with fosinopril before each apheresis session.
- If this treatment is administered at the same time as therapy to make you less allergic to insect venom (desensitisation therapy, e.g. against wasp and bee stings). This is because life-threatening hypersensitivity reactions may occur. These can be avoided by temporarily suspending treatment with fosinopril.
- Because this treatment has been associated with liver abnormalities which have sometimes resulted in death. If jaundice occurs or marked increases in certain liver-specific substances are found in the blood, fosinopril use should be stopped and appropriate follow-up treatment should be started.
- Because blood abnormalities may occur. Blood abnormalities that can occur as a result of using fosinopril include a drop in the number of blood platelets, accompanied by bruising and susceptibility to bleeding (thrombocytopenia), changes in the number of red blood cells, possibly accompanied by anaemia, a decrease in the amount of certain white blood cells with sudden high fever, severe sore throat and mouth ulcers (agranulocytosis) and a lack of white blood cells accompanied by increased susceptibility to infection (neutropenia). Treatment should be stopped if neutropenia occurs or is suspected.
- If you suffer from a connective tissue disorder (e.g. lupus erythematosus, an inflammation-like disease of the skin, internal organs, joints, kidney and heart), if you are using medicines that suppress the body’s immune system (immunosuppressants), or if you are on treatment with allopurinol (anti-gout medication) or procainamide (used to treat heart rhythm disorders). You should use fosinopril with extreme caution, particularly if you have poor kidney function. This is because, in some instances, severe infections have developed which, in some cases, failed to respond to antibiotic treatment. Patients are advised to have their white blood cell count periodically checked and to report any symptoms indicative of infection.
- Dry cough may occur during treatment with fosinopril, which disappears when treatment is stopped.
- If you need to undergo major surgery and/or an anaesthetic. An excessive drop in blood pressure may occur in such cases. Before any surgical interventions, you should therefore tell the anaesthetist (in charge of administering the anaesthetic) that you are using fosinopril.
- If you have poor kidney function, if you have diabetes mellitus, if you are also using potassium-sparing diuretics (water tablets), potassium supplements, potassium-containing salt substitutes or any other medicines that increase the amount of potassium in your blood, or if you are elderly. In such cases, fosinopril can increase the amount of potassium in your blood. This may even occur without any apparent cause. If you have to use one or several of the medicines listed above, you are therefore recommended to have the amount of potassium in your blood regularly monitored.
- If you have diabetes and are on treatment with so-called oral (via the mouth) antidiabetics or insulin (certain agents used to treat diabetes), as fosinopril can affect the control of your blood sugar levels. For this reason, you (or your doctor) should monitor your dosage of insulin and/or oral antidiabetics (via the mouth) and, if necessary, adjust it during the first month of treatment with fosinopril.
- If you are also using lithium (an antidepressant). Combined use is generally not recommended.
- 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, etc.), 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”.

Consult your doctor if any of the above applies to you now or in the past.

Other medicines and Fosinopril sodium
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines

Note: The following statements may also apply to recently used medicines or medicines that you are about to use in the near future.

The effect of fosinopril can be enhanced if used at the same time as:
- *Water tablets (diuretics)*
  This may result in an (excessive) drop in blood pressure, causing you to feel dizzy or faint. Your doctor may decide to stop the water tablets before starting you on fosinopril.
- *Other high blood pressure medications, nitroglycerin and other nitrates*
- *Medicines used to treat depression (tricyclic antidepressant), medicines used in psychiatric disorders, some narcotics*
- *Alcohol*

The effect of fosinopril can be reduced if used at the same time as:
- *So-called sympathicomimetic agents(Ephedrine, noradrenaline or adrenaline):*
  These medicines have an effect on certain parts of the nervous system
- *Antacids*
  Antacids (e.g. aluminium hydroxide, magnesium hydroxide and simethicone) can reduce absorption of fosinopril. For this reason, there should be an interval of at least 2 hours between administering the two medications.

Fosinopril has an effect on the use of other medicines:
- *Lithium*
  The amount of lithium (used in certain forms of depression) in the blood may be increased. This particularly applies if water tablets known as thiazide diuretics are also used. Nevertheless, if a combination of fosinopril and lithium is still required, lithium levels must be well monitored.
- *Medicines used in diabetes*
  Combined use of ACE inhibitors and antidiabetic medications (insulin, antihyperglycaemic tablets) can lead to a further reduction in blood sugar levels. This occurs at the start of combined treatment and in patients with poor kidney function.
- *Immunosuppressants, cytostatics, systemic corticosteroids or procainamide, allopurinol*
  Combination of fosinopril sodium and immunosuppressants and/or other medicines that can cause leukopenia (lack of white blood cells accompanied by increased susceptibility to infection) should be avoided.

Other medicines that have an effect on fosinopril:
- *Anti-inflammatories (NSAIDs), including acetylsalicylic acid ³ 3 g per day*
  Long-term use of these anti-inflammatory agents such as indomethacin, ibuprofen and aspirin can reduce the antihypertensive (blood pressure-lowering) effect. In addition, the amount of potassium in the blood is increased by combining these medicines, possibly resulting in worsening kidney function. These effects usually disappear when treatment is stopped.
- 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)
- Racecadotril (a medicine used to treat diarrhea), medicines used to prevent organ transplant rejection and for cancer (e.g., temsirolimus, sirolimus, everolimus), and vildagliptin (a medicine used to treat diabetes). The risk of angioedema may be increased.
- Angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings “Do not take Fosinopril sodium” and “Warnings and precautions”).”

Fosinopril sodium with food and drink and alcohol
Some people may experience dizziness as a result of an excessive drop in blood pressure, particularly at the start of treatment, whenever there is a dose increase or change in medication or in combination with the effects of alcohol.

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 before you become pregnant or as soon as you know you are pregnant and will advise you to taken another medicine instead of fosinopril. Fosinopril 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.

Breastfeeding
Tell your doctor if you are breast-feeding or about to start breast-feeding. Fosinopril 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
Some people may experience dizziness as a result of an excessive drop in blood pressure, particularly at the start of treatment, whenever there is a dose increase or or change in medication, or in combination with the effects of alcohol.
Find out whether this applies to you before you start driving or using machines.

Fosinopril sodium contains lactose
If your have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Fosinopril sodium contains sodium
This medicinal product contains less than 1 mmol sodium (23 mg) per each tablet, that is to say essentially ‘sodium-free’.

3. How to take Fosinopril sodium

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

The recommended dose of 10 mg has not been studied in patients with severe NYHA class IV heart failure or in patients over 75 years of age receiving treatment for heart failure.
It is recommended to start treatment at a reduced (5 mg) dose in patients at increased risk of hypotension (excessively low blood pressure), such as patients with severe heart failure (NYHA class IV), patients over 75 years of age receiving treatment for heart failure, patients with severe kidney and/or severe liver impairment and patients on treatment with water tablets (diuretics).

If you are being given Fosinopril sodium for high blood pressure, you will usually start on one 10 mg tablet, once daily. Your doctor will determine whether the effect of Fosinopril sodium is sufficient. Some users will need a lower or even higher dose (ranging from 10 to 40 mg per day). If necessary, your doctor will adjust the dosage.
If you are using water tablets, these should normally be stopped 2 to 3 days before treatment with fosinopril is started. If this is not possible, treatment should be started at a dose of 10 mg and it is recommended that treatment with fosinopril sodium tablets be started for a few hours under medical observation, until the blood pressure is stable.

If you are being given Fosinopril sodium for heart failure, you will also start (in most cases) on one 10 mg tablet once daily. Treatment should be started under close medical observation. Depending on the result, your doctor will then gradually increase the dose to 40 mg a day. If you have very poor function of the kidneys, liver or heart, your doctor may decide to start with Fosinopril sodium 5 mg.

The use of Fosinopril sodium is not recommended in children and adolescents. There is limited clinical trial experience of the use of fosinopril in hypertensive children aged 6 years and above The optimum dosage has not been determined in children of any age. An appropriate dose strength is not available for children weighing less than 50 kg.

Directions for use
Take the tablets with half a glass of water. You can take the tablets before, during or after a meal. You should take Fosinopril sodium once a day at approximately the same time each day. The effect of the tablets lasts for 24 hours.

Duration of treatment
You will generally have to use Fosinopril sodium over the long term. Closely follow your doctor’s instructions. It is important that you keep taking your medicines, even if you feel no effect.

If you stop taking Fosinopril sodium tablets
You will not experience any withdrawal symptoms if you suddenly stop using Fosinopril sodium. However, the desired effect will no longer occur, in addition the risk of complication due to high blood pressure, especially in the heart, brain and kidneys may occur. On no account should you stop using this medicine without consulting your doctor.

If you take more Fosinopril sodium than you should:
If you have taken or used too much Fosinopril sodium, contact your doctor or pharmacist immediately. If you have taken too many tablets, you may experience dizziness or fainting.

If you forget to take Fosinopril Sodium:
Do not take a double dose to make up for a forgotten dose. For your treatment, it is important that you take - on a daily basis - the tablets prescribed to you by your doctor. If you happen to forget to take your tablets, you can still take the forgotten dose unless it is time for your next dose.

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. The following side effects have been reported at the approximate frequencies shown:

Common (affects 1 to 10 users in 100)
- upper respiratory tract infection, soar throat, inflammation of the lining of the nose, viral infection
- altered mood, sleep disorder
- dizziness, headache, pins and needles, alterations in taste
- eye disorders, visual disturbances
- rapid heartbeat (tachycardia), heart rhythm disorders, palpitations, chest pain from the heart (angina pectoris), cough, sinus disorder
- nausea, vomiting, diarrhoea, stomach pain, indigestion
- skin rash, sudden fluid accumulation in the skin and mucous membranes (e.g. throat, tongue), breathing difficulties and/or itching and skin rash, usually due to an allergic reaction (angioedema), skin inflammation (dermatitis)
- pain in bones, muscles or joints
- urination disorder
- impotence
- low blood pressure
- dizziness on standing
- chest pain (non-heart related), weakness
- liver effects.

Uncommon (affects 1 to 10 users in 1,000)
- changes in the blood count, such as haemoglobin, haematocrit
- reduced appetite, gout, excessively high potassium concentrations (hyperkalaemia)
- depression, confusion
- stroke, somnolence, fainting, tremor
- earache, ringing in the ears (tinnitus), dizziness
- heart attack or brain haemorrhage (CVA) cardiac arrest, heart rhythm disorders, conduction disturbances
- increased blood pressure (hypertension), shock, obstruction of the blood supply to body tissue (ischaemia)
- shortness of breath (dyspnoea), inflamed sinuses (sinusitis), inflammation of the airways (tracheobronchitis)
- dry mouth, constipation, flatulence
- itching, increased sweating (hyperhidrosis), whealing (urticaria)
- kidney failure, increased protein excretion in the urine (proteinuria)
- fever, sudden death, pain in the thorax (chest)
- weight increase, changes in blood tests that show how well you’re liver and kidneys are working

Rare (affects 1 to 10 users in 10,000)
- changes in the blood count, such as anaemia, a blood abnormality (lack of white blood cells) accompanied by increased susceptibility to infection (leukopenia and neutropenia), increase in the number of eosinophil white blood cells (eosinophilia), lymph gland disease (lymphadenopathy), a blood abnormality (lack of blood platelets) accompanied by bruising and susceptibility to bleeding (thrombocytopenia)
- speech disorders (dysphasia), memory disorders, disorientation
- hot flushes, bleeding (haemorrhage), peripheral vascular disorders
- tight-chestedness caused by airway muscle spasms (bronchospasm), nosebleed (epistaxis), inflammation of the larynx (voice box) / hoarseness, pneumonia, lung disease (pulmonary congestion)
- mouth ulcers, inflamed pancreas (pancreatitis), swollen tongue, abdominal swelling, problems in swallowing (dysphagia)
- liver inflammation (hepatitis)
- red pinpoint bleeding into the skin (ecchymosis)
- aching joints
- weakness in one limb

Very rare (affects less than 1 user in 10,000)
- changes in the blood count, such as agranulocytosis (a very severe blood abnormality (lack of white blood cells) accompanied by sudden high fever, severe sore throat and mouth ulcers)
- fluid accumulation in the gut (intestinal angioedema), bowel obstruction; complete (ileus) or partially complete (subileus)
- Acute kidney failure
- liver failure
- low levels of salt in the blood

Not known (frequency cannot be estimated from the available data):
- appetite disorder, weight fluctuation
- abnormal behaviour
- balance disorder
- sudden stopping of the heart beat and breathing
- severe increase in blood pressure
- impairment of the voice, chest pain (pleuritic pain)
- muscular weakness
- Prostatic disorder
- pain
- abnormal liver function test

A complex of symptoms has been reported, whereby one or more of the following symptoms may occur: fever, inflamed blood vessels (vasculitis), muscle pain, aching joints (arthralgia/ arthritis), certain blood abnormalities (including positive antinuclear antibodies (ANA), increased sedimentation of red blood cells (ESR), eosinophilia and leukocytosis), skin rash, hypersensitivity to light or other skin disorders.

Reporting of side effects
If you get any side effects, talk to your doctoror pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via
Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard. 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

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

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

This medicinal product does not require any special storage conditions.

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 protect the environment.

6. Contents of the pack and other information

What Fosinopril sodium contains
- The active ingredient is fosinopril sodium. Each tablet contains either 10 mg or 20 mg fosinopril sodium.
- The other ingredients are: lactose, microcrystalline cellulose, crospovidone, sodium stearyl fumarate and povidone (K-30).

What Fosinopril sodium looks like and contents of the pack

Fosinopril sodium 10 mg tablets:
White to off-white, flat, capsule-shaped, uncoated tablets, with a scoreline with notched sides on both sides, debossed on one side of the tablet with ‘X’ and ‘77’ on either side of the scoreline, and plain on the other side
The tablets can be divided into two equal halves.

Fosinopril sodium 20 mg tablets:
White to off white, round, biconvex, uncoated tablets with an “X” on one side and “84” on the other side.
The tablets are packaged in blister PVC/ PE/ PVdC/ aluminium or plastic bottles with a high density polyethylene (HDPE)

Pack size:
PVC/ PE/ PVdC/ Aluminium blisters: 10,14,20,21,28,30,42, 50, 56, 60, 90, 98, 100 and 400 tablets
HDPE bottles with polypropylene cap containing silica gel sachet and cotton coil: 28 and 500 tablets

Not all pack sizes may be marketed.

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This leaflet was last revised in 01/2023.