

PACKAGE LEAFLET: Information for the patient

FOSIP

Tablets – 10 mg, 20 mg

(Fosinopril sodium)

Read all of this leaflet carefully before you start taking this medicine.

- 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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Fosip is and what it is used for
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1. WHAT FOSIP IS AND WHAT IT IS USED FOR

Fosip tablets contain the active substance fosinopril sodium which is a prodrug that belongs to a group of medicines called ACE (angiotensin converting enzyme) - inhibitors and make it easier for the heart to pump blood around the body. It binds to the ACE in the body, thereby inhibiting the formation of angiotensin II, a substance which raises the blood pressure.

Fosip is used in:

- The treatment of high blood pressure (hypertension);
- The treatment of heart failure.

2. BEFORE YOU TAKE FOSIP

Do not take Fosip if:

- You are allergic (hypersensitive) to fosinopril sodium, other ACE inhibitors or any of the excipients of this medicine (listed in section 6);
- 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;
- You have narrowing of the blood vessels in one or both kidneys;
- You are in shock due to heart problems (cardiogenic shock);
- You have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren;
- You have taken or are currently taking sacubitril/valsartan, a medicine used to treat a type of chronic heart failure in adults, as the risk of angioedema (rapid swelling under the skin in an area such as the throat) is increased;
- You are more than 3 months pregnant (it is also better to avoid Fosip in early pregnancy – see ‘Pregnancy and Breastfeeding’ section).

Take special care with Fosip

Ask your doctor before you take Fosip.

Fosip should be used with caution:

- If you have kidney problems or are undergoing dialysis treatment;
- If you have liver problems;
- If you are going to undergo treatment for hypersensitivity to bee or wasp stings;
- 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 (thickness of heart muscle wall);
- If you have become dehydrated from having recently suffered from vomiting or diarrhoea or treatments with medicines like diuretics;
- If you are on a low salt diet;

- 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 Fosip before each apheresis session;
- If you are Afro-Caribbean. If you are taking Fosip 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. Fosip 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;
- 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;
- 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 Fosip;
- 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);

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

Taking other medicines

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

It is particularly important to inform your doctor that you are taking:

- Other blood pressure lowering medicines including methyldopa, betablockers (e.g. atenolol), calcium antagonists (e.g. verapamil) or diuretics (e.g. furosemide) as it may lead to an increase in the blood pressure lowering effects;
- 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 sulfamethoxazole with trimethoprim 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);
- 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 “Take special care with Fosip”;
- Painkillers and anti-inflammatory medicines of the NSAID type (e.g. aspirin or indometacin) as they can reduce the effect of Fosip;
- Antacids (to relieve indigestion) stop the body absorbing Fosip. There should be at least 2 hours between taking the antiacid and Fosip;
- Insulin and medicines used in diabetes, as Fosip may increase the effect of these, especially during the first week of combination treatment;
- Lithium (used for manic depression), as Fosip may increase the concentration of lithium in the blood;
- Immunosuppressants (these reduce the body’s natural defence system) such as azathioprine, cytostatics and systemic corticosteroids or procainamide. Using them together may affect some blood counts;
- Medicines known as sympathomimetics e.g. salbutamol, ephedrine and some medicines for colds, coughs or flu symptoms which may contain these ingredients;
- Allopurinol (used to treat gout);
- Tricyclic antidepressants e.g. amitriptyline or dosulepin, or antipsychotics (used for psychiatric problems) e.g. flupenthixol;

- Glyceryl trinitrate and other nitrates used to treat angina (chest pain).

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.

This list is not complete and there may be other drugs that may interact with Fosip.

Do not start another treatment without telling your doctor first.

Taking Fosip with food and drinks

Alcohol may interact with Fosip by increasing the hypotensive effect, therefore it should not be consumed during the time of treatment.

Pregnancy

Tell your doctor or pharmacist, if you are pregnant, think you may be pregnant or are planning to become pregnant.

Your doctor will advise you to stop taking Fosip before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Fosip. Fosip 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 breastfeeding or about to start breastfeeding. Fosip is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breastfeed, 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, do not drive or use machinery during treatment with Fosip.

Important information about some of the excipients of Fosip

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

Blood tests

Fosip may interfere with the results of some blood tests.

Tell your doctor that you are taking Fosip.

3. HOW TO TAKE FOSIP

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

The tablets should be swallowed with at least half glass of water in the morning with or without food. Do not chew the tablets.

The recommended dose is:

Adults and Elderly

The usual dose is 10 mg once daily, up to a maximum of 40 mg once daily. Fosip may be taken alone or in combination with a diuretic 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 Fosip.

Occasionally some people start their treatment in hospital.

If you take more Fosip than you should

Symptoms associated with overdose may include severe hypotension and renal failure.

Immediately contact your doctor or the nearest hospital.

If you forget to take Fosip

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 stop taking Fosip

Do not stop the treatment without consulting your doctor first. If you stop taking Fosip, your blood pressure may increase.

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

4. POSSIBLE SIDE EFFECTS

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

Common side effects (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 (angina pectoris);
- Viral infections;
- Altered mood, 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 (orthostatic hypertension);
- Runny nose;
- A dry persistent cough, which does not produce phlegm on the chest;
- Feeling or being sick, diarrhoea, abdominal pain, indigestion problems;
- Muscle, bone or joint pain;
- Problems urinating;
- Sexual problems;
- Tiredness, chest pain not related to the heart, swelling of the hands and feet, lack of energy, weakness;
- Rash, swelling, dermatitis;
- Increase in LDH, alkaline phosphatase, bilirubin, or transaminases seen in blood tests.

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

- Changes in the blood count, such as haemoglobin, haematocrit;
- Reduced appetite, gout, excessively high potassium concentrations (hyperkalaemia);
- Stroke, fainting, drowsiness;
- Earache, ringing in the ears (tinnitus), dizziness;
- Increased blood pressure (hypertension), shock, obstruction of the blood supply to body tissue (ischaemia);
- Shortness of breath (dyspnoea), inflammation of the sinuses (sinusitis), inflammation of the airways (tracheobronchitis);
- Dry mouth, constipation, flatulence;
- Increased sweating, itching, urticaria;
- Kidney failure, increased protein excretion in the urine (proteinuria);
- Fever, sudden death, thoracic pain;
- Weight increase, changes in blood tests that show how well you're liver and kidneys are working.
- Heart attack or brain hemorrhages, cardiac arrest, heart rhythm disorders, conduction disturbances.
- Depression, confusion.

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

- Changes in the blood count, such as anaemia, increase in the number of eosinophils (eosinophilia), lack of white blood cells accompanied by increased susceptibility to infection (leukopenia and neutropenia), lymph gland disease (lymphadenopathy), a blood abnormality (lack of blood platelets) accompanied by bruising and susceptibility to bleeding (thrombocytopenia);
- Problems in the ability to select the correct words (dysphasia), memory problems, disorientation;
- Hot flushes, bleeding (haemorrhage), peripheral vascular disorders;
- Tight-chestedness caused by airway muscle spasms (bronchospasm), nosebleed (epistaxis), 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);
- Arthritis;
- Weakness in limbs.

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

- Severe reduction in number of white blood cells (agranulocytosis);
- Fluid accumulation in intestines (intestinal angioedema), bowel obstruction which can be complete (ileus) or partially complete (subileus);
- Liver failure;
- Acute renal failure.

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

- Appetite disorder, weight fluctuation;
- Abnormal behaviour;
- Balance problems;
- Abnormal liver function test;
- Pain;
- Severe increase in blood pressure;
- Sudden stopping of the heartbeat and breathing.

Talk to your doctor or pharmacist, if you get any of these side effects or any of side effects not listed in this leaflet.

5. HOW TO STORE FOSIP

Keep out of the sight and reach of children!

Do not use Fosip after the expiry date which is stated on the package.

Do not store above 25°C!

Keep in the original package to protect it from light and humidity.

6. FURTHER INFORMATION

What Fosip contains

The active substance is fosinopril sodium.

Each 10 mg Fosip tablet contains 10 mg of fosinopril sodium.

Each 20 mg Fosip tablet contains 20 mg of fosinopril sodium.

The excipients are: lactose, croscarmellose sodium, povidone, microcrystalline cellulose, crospovidone, sodium stearyl fumarate.

Contents of the pack

Fosip 10 mg: Box with 30 tablets.

Fosip 20 mg: Box with 30 tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania.

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