Package leaflet: Information for the user

Fosinopril Actavis 10 mg tablets
Fosinopril Actavis 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 Actavis is and what it is used for

Fosinopril Actavis belongs to a group of medicines called ACE inhibitors. Fosinopril Actavis lowers the blood pressure, and reduces the work-load of the heart in patients with heart failure.

Fosinopril Actavis is used in the treatment of
- high blood pressure
- heart failure (when the heart cannot pump enough blood around the body).

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

Do not take Fosinopril Actavis
- if you are allergic to fosinopril, other ACE inhibitors or any of the other ingredients of this medicine (listed in section 6).
- if you have previously had swollen legs, arms, face, mucous membranes or tongue (angioedema) in connection with use of ACE inhibitors or for some other, unknown reason, or if anyone in your family has had angioedema (this condition may be hereditary)
- if you are more than 3 months pregnant. (It is also better to avoid Fosinopril Actavis 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
Talk to your doctor or pharmacist before taking Fosinopril Actavis

- if you suffer from prolonged bouts of diarrhoea or vomiting, use potassium supplements, potassium-sparing medicines, potassium-containing salt substitutes, have a high level of potassium in your blood (as determined by blood tests) or are on a low salt diet
- if you take diuretic medication (water tablets). Your doctor may discontinue diuretic therapy and correct volume and/or salt depletion before starting treatment with Fosinopril Actavis
- if you have a weak heart (heart failure) or heart disease (e.g. certain heart valve defects or thickening of the heart muscle)
- if you suffer from circulatory disorders of the brain
- if you have low blood pressure
- if you have reduced kidney function, narrowing of the blood vessels to the kidneys, or liver disease. Your doctor may need to monitor you and change the dose of your medicine
- if you recently had a kidney transplant
- if you have diabetes. You may have to check your blood sugar more often in the first month of the treatment. See also “Other medicines and Fosinopril Actavis” below.
- if you are undergoing treatment for hypersensitivity to bee or wasp stings (hyposensitisation treatment)
- if you are on haemodialysis. Tell your doctor so that a technique that does not cause hypersensitivity reactions can be chosen
- if you are having a procedure which removes bad cholesterol from your blood (LDL apheresis), you should not take Fosinopril Actavis. This is in order to avoid hypersensitivity reactions
- if you are taking lithium medicine used for the treatment of mania or depression
- if you have a persistent, dry cough
- if you are black, as ACE inhibitors are often less effective in black patients than in patients with other skin colours.
- 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.
      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 Actavis”.
- 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.

At the start of the treatment and if you are taking other blood pressure reducing medicines at the same time, Fosinopril Actavis may cause symptoms of too low blood pressure (dizziness, fainting). Tell your doctor if these symptoms appear. Increasing the frequency of medical check-ups may be necessary in the beginning of treatment and/or during the period of dosage adjustment. You should not skip these visits even if you feel well. Your doctor will determine the frequency of control examinations.

Tell your doctor or dentist that you are being treated with Fosinopril Actavis before undergoing any anaesthetic for surgical or dental treatment, as there is a risk of your blood pressure becoming very low during the anaesthetic.

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

Other medicines and Fosinopril Actavis

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Some other medicines may affect or be affected by Fosinopril Actavis.
It is especially important for your doctor to know if you are already being treated with any of the following medicines:

- other medications that lower the blood pressure (other blood pressure lowering medicines, nitrates used in treatment of coronary artery disease, tricyclic antidepressants, phenothiazine used to treat psychoses, and barbiturates used to treat epilepsy and anesthetics)
- diuretics (water tablets)
- 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)
- lithium (used to treat manic-depressive disease) because Fosinopril Actavis can increase lithium levels in your blood. Your doctor must therefore monitor your lithium levels carefully.
- NSAIDs such as acetylsalicylic acid, ibuprofen or ketoprofen on a regular basis and for long periods (NB: low doses of acetylsalicylic acid to prevent blood clots can be used safely with Fosinopril Actavis)
- sympathomimetic drugs (medicines that stimulate the central nervous system) which may also be found in some cough/cold remedies and asthma medication
- antidiabetic medicines (both insulin and oral products)
- allopurinol (used to treat gout), procainamide (used to treat irregular heart beat), medicines to treat cancer or medicines that inhibit your body's immune system (immunosuppressants)
- 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"

You should wait at least two hours between taking Fosinopril Actavis and antacids (a type of medicine used for heartburn and acid regurgitation) or simethicone (used to relieve the symptoms of excessive gas in the gastrointestinal tract).

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 Actavis" and "Warnings and precautions").

Fosinopril Actavis with food, drink and alcohol
Fosinopril Actavis should be taken with fluid (e.g. ½ a glass of water) and can be taken with or without food.
Alcohol can increase the blood pressure lowering effect of Fosinopril Actavis.

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 Actavis before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Fosinopril Actavis. Fosinopril Actavis 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 Actavis 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 patients may experience dizziness (due to an excessive blood pressure lowering effect), which may affect the ability to drive and use machines. This occurs especially at the start of the treatment or when increasing the dose.

Fosinopril Actavis 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.

Fosinopril Actavis contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Fosinopril Actavis

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

High blood pressure:
The recommended starting dose is 10 mg once daily. The dose may be increased to 40 mg once daily if needed.

Heart failure:
The recommended starting dose is 10 mg once daily. The dose may be increased to 40 mg once daily if needed.

Patients with liver and kidney problems and elderly
The recommended starting dose is 10 mg once daily.

Use in children and adolescents
Fosinopril Actavis is not recommended in children and adolescents under 18 years.

If you take more Fosinopril Actavis than you should
If you have taken more medicine than you should, or if children have been taking medicine by accident, please contact your doctor or hospital to get an opinion of the risk and advice on action to be taken.
Overdose can cause symptoms such as a fall in blood pressure with dizziness and fainting.

If you forget to take Fosinopril Actavis
Do not take a double dose to make up for a forgotten dose. Instead, take your usual dose at the next usual time.

If you stop taking Fosinopril Actavis
Do not stop taking Fosinopril Actavis unless your doctor advises you to do so. If you stop taking Fosinopril Actavis, your blood pressure may increase and affect the function of your heart and kidneys.

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.

Stop taking Fosinopril Actavis and contact your doctor *immediately*
- if you get swelling of the face, lips, tongue and/or throat, rash, itching, shortness of breath or difficulty swallowing (angioedema) (common side effects)
- if you get an infection with symptoms such as fever with a much reduced general condition, or fever with sore throat or voiding problems (agranulocytosis) (very rare side effects)
- yellowing of the skin and whites of eyes (jaundice) that may be signs of liver disease (very rare side effects).

Contact a doctor as soon as possible if you experience
- dizziness/fainting, tiredness or weakness (signs of low blood pressure) (common side effects)
- dry cough which is persistent for a long time (common side effect).

Other side effects include

Common (may affect up to 1 in 10 people):
- upper respiratory tract infection, sore 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
- fast heart beat, heart rhythm disorders, chest pain from the heart (angina pectoris), palpitations
- too low blood pressure
- sinus disorder
- nausea, vomiting, diarrhoea, stomach pain, indigestion
- skin rash, skin inflammation
- pain in bones, muscles or joints
- urination disorder
- sexual dysfunction
- chest pain (not from the heart), mental tiredness, oedema
- liver effects.

Uncommon (may affect up to 1 in 100 people):
- inflammation of the sinuses, lining of the throat and windpipe
- alteration of blood values
- decreased appetite, weight gain, gout, increased potassium levels
- depression, abnormal behaviour, confusion, sleepiness, stroke (cerebrovascular accident), fainting, trembling
- heart attack, sudden stopping of the heart beat, heart conduction disturbances
- high blood pressure, shock, reduced local blood circulation (transient ischaemic attack (TIA))
- earache, buzzing in the ears, spinning sensation
- shortness of breath
- constipation, mouth dryness, flatulence
- sweating, itching, urticaria
- reduced kidney function, protein in the urine
- impotence, abnormal breast enlargement
- fever, swelling of arms and legs, chest pain

Rare (may affect up to 1 in 1,000 people):
- inflammation of the voice box (laryngitis)/hoarseness.
- inflammation of the lungs
- temporary anaemia, enlarged lymph glands, alterations in the number of platelets and some white cells in the blood
- speech disturbances, memory disturbances, disorientation
- hot flashes, bleeding, blood vessel disease
- cramp in the windpipe, nosebleed, congestion of blood in the lungs

- mouth ulcers, swollen tongue, difficulty swallowing, bloating, inflammation of the pancreas
- inflammation of the liver
- bruises
- joint pain
- prostate problems
- weakness in arms or legs
- small increases in haemoglobin, decreased sodium levels

Very rare (may affect up to 1 in 10,000 people):
- swelling of blood vessels in the intestine (which is experienced as abdominal pain, with or without nausea and vomiting), intestinal obstruction
- kidney failure

Not known (frequency cannot be estimated from the available data):
- hypersensitivity reactions
- appetite disorder, weight fluctuation
- 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
- pain
- abnormal liver function test.

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 national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Fosinopril Actavis

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

Do not store above 25 °C.

Blister pack
Store in the original package in order to protect from moisture.

Tablet containers
Keep the container tightly closed in order to protect from moisture.

Do not use this medicine after the expiry date which is stated on the label, carton, and blister after EXP. 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 protect the environment.

6. Contents of the pack and other information

What Fosinopril Actavis contains

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

- The other ingredients are lactose monohydrate, croscarmellose sodium, pregelatinised maize starch, microcrystalline cellulose and glycerol dibehenate.

What Fosinopril Actavis looks like and contents of the pack

Fosinopril Actavis 10 mg tablets are white to off-white, round tablets, marked “FL10” and 8 mm in diameter.
Fosinopril Actavis 20 mg tablets are white to off-white, round tablets, marked “FL20” and 8 mm in diameter.

Pack sizes
Blister packs: 10, 14, 20, 28, 30, 42, 50, 98 and 100 tablets.
Plastic bottles: 50, 100, 250 and 500 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

For RMS:
Actavis Group PTC ehf.
Dalshraun 1
220 Hafnarfjörður
Iceland

Manufacturer
Balkanpharma Dupnitsa AD
3 Samokovsko Shose Str.
Dupnitsa 2600
Bulgaria

This medicine is authorised in the Member States of the European Economic Area under the following names:

Estonia, Latvia, Sweden	Fosinopril Actavis
Lithuania	Fosinopril Actavis 20 mg tabletės

This leaflet was last revised in 2025-05-14.