

Package leaflet: Information for the user

Fosinopril Medis 10 mg tablets

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

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

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

Fosinopril Medis 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 Medis

Do not take Fosinopril Medis

- 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 Medis 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 Medis

- 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 Medis
 - 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 Medis”.
 - 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 Medis. 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 Medis”.
- 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 Medis 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 Medis 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 Medis 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 Medis

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 Medis.

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, 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 Medis 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 Medis)
- 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 Medis 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 Medis" and "Warnings and precautions").

Fosinopril Medis with food, drink and alcohol

Fosinopril Medis 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 Medis.

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

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 Medis is not recommended in children and adolescents under 18 years.

If you take more Fosinopril Medis 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 Medis

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 Medis

Do not stop taking Fosinopril Medis unless your doctor advises you to do so. If you stop taking Fosinopril Medis, 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 Medis 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 Medis

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 bottle

Unopened bottles: Do not use this medicine after the expiry date which is stated on the package. The expiry date refers to the last day of that month.

After opening: Keep the bottle tightly closed in order to protect from moisture. Use within 100 days after first opening the bottle.

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 Medis 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 Medis looks like and contents of the pack

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

Fosinopril Medis 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

(For RMS)

Teva B.V.
Swensweg 5
Haarlem, 2031GA
The Netherlands

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:

Austria	Fosinopril Actavis 10 mg Tabletten
	Fosinopril Actavis 20 mg Tabletten
Sweden	Fosinopril Medis

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