

PACKAGE LEAFLET: INFORMATION FOR THE USER

MONOPRIL

10 mg & 20 mg Tablets

FOSINOPRIL

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

1. What Monopril is and what it is used for
2. Before you take Monopril
3. How to take Monopril
4. Possible side effects
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1. WHAT MONOPRIL IS AND WHAT IT IS USED FOR

MONOPRIL contains the active ingredient fosinopril sodium which is used to treat high blood pressure (hypertension) and heart failure. MONOPRIL tablets belong to a group of medicines called ACE inhibitors and make it easier for the heart to pump blood around the body.

2. BEFORE YOU TAKE MONOPRIL

Do not take Monopril:

- If you have had an allergic reaction (hypersensitivity reaction) to fosinopril, other ACE inhibitors or any of the excipients of medicine Monopril (see section 6. Further information)
- If one of your family members previously had swollen legs, arms, face, mucous membranes or tongue and / or throat (angioedema), regardless of treatment with ACE inhibitors,
- If you suffer from a narrowing of the blood vessels to one or both kidneys,
- If you are in a state of shock due to heart failure (cardiogenic shock)
- If you are more than 3 months pregnant. (It is also better to avoid fosinopril sodium in early pregnancy – see 'Pregnancy and breast feeding' section.)

Take special care with Monopril:

- if you have kidney problems
- if you have liver problems
- if you are having dialysis
- if you are going to undergo treatment for hypersensitivity to bee or wasp stings (hyposensitisation)
- 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 (enlarged heart muscle) • if you have become dehydrated from having recently suffered from vomiting or diarrhea
- if you are on a low salt diet
- if you are Afro-Caribbean. If you are taking Tablets 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. Fosinopril sodium 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 (see pregnancy section).
- Tell your doctor or dentist before undergoing any surgery or dental treatment that you are being treated with fosinopril sodium, as there is a risk of your blood pressure sinking very low during the anesthetic.

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. It is very important that you tell your doctor if you are taking any of the following medications:

- Medicines to lower high blood pressure, including methyldopa, beta-blockers (for example, atenolol), calcium antagonists (for example, verapamil) or diuretics - medicines for increased urination (for example, furosemide), as this may lead to increased effects on blood pressure,
- Potassium-sparing diuretics (for example, spironolactone, triamterene or amiloride), potassium supplements or salt substitutes containing potassium, because Monopril may affect the increase in the level of potassium. In these patients it is necessary to monitor the level of potassium in the blood,
- Painkillers and anti-inflammatory medicines in the class of NSAIDs (for example, aspirin, or indomethacin) because they may reduce the effect of fosinopril,
- Antacids (to relieve indigestion), because they prevent the absorption of fosinopril.
- Insulin or oral therapy of diabetes, because Fosinopril may increase the effect of these medicines, especially in the first two weeks of combination therapy,
- Lithium (used for the treatment of manic depression), as fosinopril may affect the concentration of lithium in the blood,
- Immunosuppressants (they reduce the natural defense system of the body) such as azathioprine because concomitant administration of these medicines can affect the concentration of certain blood cells in the blood,
- Diuretics (medicines for increased urination), because when applied with fosinopril may cause lowering of blood pressure.

Taking food and drink with MONOPRIL

Food does not affect the activity of the drug Monopril, and the drug can be taken before or after meals.

Moderate amounts of alcohol also do not affect the action of medicine Monopril. However you should consult with a doctor regarding the consumption of alcohol during administration of this drug.

Pregnancy and breastfeeding

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

If you experience dizziness, low blood pressure, lightheadedness or vertigo ('spinning' sensation), do not drive or use machinery during treatment with fosinopril sodium.

Other warnings

In case of intolerance to some sugars, contact your doctor before taking this medicine, as it contains lactose.

Fosinopril sodium may interfere with the results of some blood tests. Tell your doctor that you are taking MONOPRIL.

3. HOW TO TAKE MONOPRIL

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Swallow the tablets whole with at least ½ a glass of water in the morning with or without food. Do not chew or crush the tablets.

The recommended dose is:

Adults: The usual dose is 10mg once daily, up to a maximum of 40mg once daily. MONOPRIL Tablets may be taken alone or in combination with a diuretic (water tablet) 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 fosinopril sodium. Occasionally some people start their treatment in hospital.

Use in children and adolescents under 18 years old: Not recommended.

If you take more Monopril than you should

Contact your doctor. If possible, bring a tablet, this instruction or packaging with you to show the doctor what you have taken.

If you forget to take Monopril

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 Monopril

Do not stop taking MONOPRIL unless your doctor advises you to do so. If you stop taking fosinopril sodium, your blood pressure may increase.

If you have any further questions about the application of Monopril, talk to your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Monopril may cause side effects.

Stop taking MONOPRIL and contact your doctor immediately if you experience swelling of the face, lips, tongue and/or throat, rash, itching, breathlessness or difficulty swallowing (angioedema).

Tell your doctor if you notice any of the following side effects or they get worse:

- Common (may affect up to 1 in 10 people):

infection of the upper respiratory tract (mouth, nose, throat or voice box), sore throat, runny nose, viral infections, bacterial infection of the lungs (pneumonia), laryngitis (Inflammation of larynx (voice box) lining and vocal cords), sinusitis (inflammation of the sinus), inflammation of the trachea and the bronchi, altered moods, sleep disorders, dizziness, headaches, pins and needles, eye disorders or problems with sight, quick or irregular heartbeat, chest pain, feeling faint on standing up due to reduced blood pressure, low blood pressure, cough, sinus disorder, feeling or being sick, diarrhea, stomach pain, indigestion, taste disturbance, rash, pain in the muscles, tendons, ligaments and bone, problems urinating, fatigue, water retention (causing swelling in the body), weakness or loss of strength,

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

fainting, shock

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

changes in types and number of blood cells (you may experience sore throat, recurring infections, nose bleeds, increased bruising), lack of appetite, appetite disorders, weight fluctuation, gout, raised levels of potassium in the blood, depression, abnormal behavior, confusion, stroke, tremor, memory problems, problems with balance, sleepiness or drowsiness, ear ache, tinnitus (ringing in the ear), vertigo ('spinning' sensation), heart attack, problems with heart rhythm or heart rate, flushing, high blood pressure or severe high blood pressure, bleeding, narrowing of the arteries in the legs, difficulty breathing or wheezing, congestion of the lungs, disorder of the voice (hoarse or weak voice), nosebleeds, inflammation of the sinuses, chest pain (not related to the heart), inflammation of the pancreas, swollen tongue, difficulty swallowing, constipation, dry mouth, flatulence, inflammation of the liver (causing yellowing of the skin or eyes or tiredness, pain in abdomen, joint or muscles), excessive sweating, bruising, itching, dermatitis (skin problems/inflammation of the skin), skin rash that may be itchy (caused by an allergic reaction, pale or red irregular raised patches on the skin (hives)), weakness of the muscles, arthritis (pain and swelling of the joints), kidney failure, problems with sexual function, abnormality or disease of the prostate gland, swelling of the soft tissue, fever with pain, increase in weight, abnormal liver function tests, bloating of the stomach, mouth problems.

If you notice any side effect, talk to your doctor or pharmacist.

5. HOW TO STORE MONOPRIL

Keep out of reach and sight of children.

Store the medicine at a temperature below 25° C, protected from light.

Shelf life: 2 years

Monopril must not be used after the expiry date stated on the packaging.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What does Monopril contain?

Active substance: Fosinopril sodium.

Monopril tablets, 28 x 10 mg: 1 tablet contains 10 mg of fosinopril sodium.
Monopril tablets, 28 x 20 mg: 1 tablet contains 20 mg of fosinopril sodium.

The other ingredients:

lactose monohydrate;
croscarmellose sodium;
starch, pregelatinized 1500;
cellulose, microcrystalline;
glycerol dibehenate.

Pharmaceutical form:

Tablets

Pharmacotherapeutic group:

ACE inhibitors

What Monopril looks like and contents of the pack

Monopril tablets, 28 x 10 mg tablets white to almost white, round, flat, non-coated, diameter 8 mm, with stamped label "FL 10" on one side.

Monopril tablets, 28 x 20 mg tablets white to almost white, round, flat, non-coated, diameter 8 mm, with stamped label "FL 20" on one side.

Monopril, tablets, 28 x 10 mg: 2 blisters (Alu / Alu) with 14 tablets in a cardboard box.

Monopril, tablets, 28 x 20 mg: 2 blisters (Alu / Alu) with 14 tablets in a cardboard box.

Regime of dispensing

The medicine is issued on prescription.

Manufacturer

PharmaSwiss doo

Batajnički drum 5A, Belgrade, Serbia