

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.

HYPERIL tablets 5 mg
HYPERIL tablets 10 mg
HYPERIL tablets 20 mg
Lisinopril

What is in this leaflet

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

1. What **HYPERIL is and what it is used for**

Hyperil contains active substance lisinopril. Lisinopril belongs to a group of medicines called ACE inhibitors (Angiotensin Converting Enzyme inhibitors). ACE inhibitors cause the body to produce less angiotensin (a hormone which tightens blood vessels and increases blood pressure), resulting in a reduction in pressure inside blood vessels and an improvement in heart function.

Lisinopril works by making your blood vessels widen. This helps to lower your blood pressure. It also makes it easier for your heart to pump blood to all parts of your body.

HYPERIL 5 mg, 10 mg and 20 mg tablets can be used for the following conditions:

- To treat high blood pressure (hypertension).
- To treat heart failure.
- If you have recently had a heart attack (myocardial infarction).
- To treat kidney problems caused by Type II diabetes in people with high blood pressure.

2. What you need to know before you take **HYPERIL**

Do not use **HYPERIL**

- If you are allergic to lisinopril or any of the other ingredients of this medicine (listed in Section 6).
- You have ever had an allergic reaction to another ACE inhibitor medicine. The allergic reaction may have caused swelling of the hands, feet, ankles, face, lips, tongue or throat. It may also have made it difficult to swallow or breathe (angioedema).
- A member of your family has had severe allergic reactions (angioedema) to an ACE inhibitor or you have had severe allergic reactions (angioedema) without a known cause.
- If you are more than 3 months pregnant. (It is also better to avoid Lisinopril 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.

Do not take **HYPERIL** if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking **HYPERIL**.

If you develop a dry cough which is persistent for a long time after starting treatment with **HYPERIL**, talk to your doctor.

Warnings and precautions

Talk to your doctor or pharmacist before taking **HYPERIL** if you:

- You have a narrowing (stenosis) of the aorta (an artery in your heart) or a narrowing of the heart valves (mitral valves).
- You have a narrowing (stenosis) of the kidney artery.
- You have an increase in the thickness of the heart muscle (known as hypertrophic cardiomyopathy).
- You have problems with your blood vessels (collagen vascular disease).
- You have low blood pressure. You may notice this as feeling dizzy or light-headed, especially when standing up.
- You have kidney problems or you are having kidney dialysis.
- You have liver problems.
- You have diabetes.
- You have recently had diarrhoea or vomiting (being sick).
- Your doctor has told you to control the amount of salt in your diet.
- You have high levels of cholesterol and you are having a treatment called "LDL apheresis".
- You must tell your doctor if you think you are (or might become) pregnant. Lisinopril 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).
- You are of black origin as **HYPERIL** may be less effective. You may also more readily get the side effect "angioedema" (a severe allergic reaction).
- 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 not sure if any of the above apply to you, talk to your doctor or pharmacist before taking **HYPERIL**.

Treatment for allergies such as insect stings

Tell your doctor if you are having or are going to have treatment to lower the effects of an allergy such as insect stings (desensitisation treatment). If you take Hyperil while you are having this treatment, it may cause a severe allergic reaction.

Operations

If you are going to have an operation (including dental surgery) tell the doctor or dentist that you are taking **HYPERIL**. This is because you can get low blood pressure (hypotension) if you are given certain local or general anaesthetics while you are taking **HYPERIL**.

Other medicines and **HYPERIL**

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription. This is because **HYPERIL** can affect the way some medicines work and some medicines can have an effect on **HYPERIL**.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Other medicines to help lower your blood pressure.
- Water tablets (diuretic medicines).
- Medicines to break up blood clots (usually given in hospital).
- Beta-blocker medicines, such as atenolol and propranolol.
- Nitrate medicines (for heart problems).
- Non-steroidal anti-inflammatory drugs (NSAIDs) used to treat pain and arthritis.
- Aspirin (Acetylsalicylic acid), if you are taking more than 3 grams each day.
- Medicines for depression and for mental problems, including lithium.
- Potassium tablets or salt substitutes that have potassium in them.
- Insulin or medicines that you take by mouth for diabetes.
- Medicines used to treat asthma.
- Medicines to treat nose or sinus congestion or other cold remedies (including those you can buy in the pharmacy).
- Medicines to suppress the body's immune response (immunosuppressants).
- Allopurinol (for gout).
- Procainamide (for heart beat problems).
- Medicines that contain gold, such as sodium aurothiomalate, which may be given to you as an injection.

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 **HYPERIL**" and "Warnings and precautions")

Pregnancy and breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking **HYPERIL** before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of **HYPERIL**.

HYPERIL 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. **HYPERIL** 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 feel dizzy or tired when taking this medicine. If this happens to you, do not drive or use any tools or machines. You must wait to see how your medicine affects you before trying these activities.

3. How to take **HYPERIL**

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

Do not take more than your recommended dose. It does not matter if you take **HYPERIL** tablets before or after food. Keep taking **HYPERIL** tablets for as long as your doctor tells you to, it is a long term treatment. It is important to keep taking **HYPERIL** tablets every day.

Taking your first dose

Take special care when you have your first dose of **HYPERIL** or if your dose is increased. It may cause a greater fall in blood pressure than later doses. This may make you feel dizzy or light-headed. If this happens, it may help to lie down. If you are concerned, please talk to your doctor as soon as possible.

Adults

Your dose depends on your medical condition and whether you are taking any other medicines. Your doctor will tell you how many tablets to take each day. Check with your doctor or pharmacist if you are unsure.

For high blood pressure

- The usual starting dose is 10 mg once a day.
- The usual long-term dose is 20 mg once a day.

For heart failure

- The usual starting dose is 2.5 mg once a day.
- The long-term dose is 5 to 35 mg once a day.

After a heart attack

- The usual starting dose is 5 mg within 24 hours of your attack and 5 mg one day later.
- The usual long-term dose is 10 mg once a day.

For kidney problems caused by diabetes

The usual dose is either 10 mg or 20 mg once a day. If you are elderly, have kidney problems or are taking diuretic medicines your doctor may give you a lower dose than the usual dose.

Children and adolescents (6 to 16 years old) with high blood pressure

HYPERIL is not recommended for children under 6 years or in any children with severe kidney problems.

The doctor will work out the correct dose for your child. The dose depends on the child's body weight. For children who weigh between 20 kg and 50 kg, the usual starting dose is 2.5 mg once a day, which can be increased to a maximum of 20mg.

For children who weigh more than 50 kg, the usual starting dose is 5 mg once a day, which can be increased to a maximum of 40mg.

If you take more HYPERIL than you should

If you take more **HYPERIL** than prescribed by your doctor, talk to a doctor or go to a hospital immediately. The following effects are most likely to happen: confusion, blurred vision, drowsiness, shock, kidney function impairment, rapid and deep breathing, heart palpitations, anxiety and cough.

If you forget to take HYPERIL

If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose.

Do not take a double dose to make up for a forgotten dose.

If you stop taking HYPERIL

Do not stop taking your tablets, even if you are feeling well, unless your doctor tells you to.

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.

If you experience any of the following reactions, stop taking **HYPERIL** and see your doctor immediately.

Severe allergic reactions (uncommon, affects 1 to 10 users in 1,000).

The signs may include sudden onset of:

- Swelling of your face, lips, tongue or throat. This may make it difficult to swallow.
- Severe or sudden swelling of your hands, feet and ankles.
- Difficulty breathing.
- Severe itching of the skin (with raised lumps).
- Severe skin disorders, like a sudden, unexpected rash or burning, red or peeling skin (very rare, affects less than 1 user in 10,000).
- An infection with symptoms such as fever and serious deterioration of your general condition, or fever with local infection symptoms such as sore throat/pharynx/mouth or urinary problems (very rare, affects less than 1 user in 10,000).

Other possible side effects:

Common (affects 1 to 10 users in 100)

- Headache.
- Feeling dizzy or light-headed, especially if you stand up quickly.
- Diarrhoea.
- A dry cough that does not go away.
- Being sick (vomiting).
- Kidney problems (shown in a blood test).

Uncommon (affects 1 to 10 users in 1,000)

- Change of colour in your fingers or toes (pale blue followed by redness) or numbness or tingling in your fingers or toes.
- Changes in the way things taste.
- Feeling sleepy.
- Spinning feeling (vertigo).
- Having difficulty sleeping.
- Stroke.
- Fast heart beat.
- Runny nose.
- Feeling sick (nausea).
- Stomach pain or indigestion.
- Skin rash or itching.
- Being unable to get an erection (impotence).
- Feeling tired or feeling weak (loss of strength).
- A very big drop in blood pressure may happen in people with the following conditions: coronary heart disease; narrowing of the aorta (a heart artery), kidney artery or heart valves; an increase in the thickness of the heart muscle. If this happens to you, you may feel dizzy or light-headed, especially if you stand up quickly.
- Changes in blood tests that show how well your liver and kidneys are working.
- Heart attack.

Rare (affects 1 to 10 users in 10,000)

- Feeling confused.
- A lumpy rash (hives).
- Dry mouth.
- Hair loss.
- Psoriasis (a skin problem).
- Changes in the way things smell
- Development of breasts in men.
- Changes to some of the cells or other parts of your blood. Your doctor may take blood samples from time to time to check whether **HYPERIL** has had any effect on your blood. The signs may include feeling tired, pale skin, a sore throat, high temperature (fever), joint and muscle pains,

swelling of the joints or glands, or sensitivity to sunlight.

- Sudden renal failure.
- Low levels of sodium in your blood (the symptoms may be tiredness, headache, nausea, vomiting)

Very rare (affect less than 1 user in 10,000)

- Sinusitis (a feeling of pain and fullness behind your cheeks and eyes).
- Wheezing.
- Low levels of sugar in your blood (hypoglycaemia). The signs may include feeling hungry or weak, sweating and a fast heart beat.
- Inflammation of the lungs. The signs include cough, feeling short of breath and high temperature (fever).
- Yellowing of the skin or the whites of the eyes (jaundice).
- Inflammation of the liver. This can cause loss of appetite, yellowing of the skin and eyes, and dark coloured urine.
- Inflammation of the pancreas. This causes moderate to severe pain in the stomach.
- Severe skin disorders. The symptoms include redness, blistering and peeling.
- Sweating.
- Passing less water (urine) than normal or passing no water.
- Liver failure.
- Lumps.
- Inflamed gut.

Not known (frequency cannot be estimated from available data)

- Symptoms of depression.
- Fainting.

Side effects in children appear to be comparable to those seen in adults.

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.

5. How to store HYPERIL

Do not store above 25°C. Store in the original pack .

Keep out of the sight and reach of children.

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

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

6. Contents of the pack and other information

What HYPERIL contains?

The active substance is lisinopril.

HYPERIL 5 mg tablets

Each tablet contains 5 mg anhydrous lisinopril (as lisinopril dihydrate). The other ingredients are: mannitol, colloidal silicon dioxide, calcium hydrogen phosphate dihydrate, pregelatinized starch, microcrystalline cellulose, titanium dioxide (E171), iron oxide red, magnesium stearate.

HYPERIL 10 mg tablets

Each tablet contains 10 mg anhydrous lisinopril (as lisinopril dihydrate). The other ingredients are: mannitol, colloidal silicon dioxide, calcium hydrogen phosphate dihydrate, pregelatinized starch, microcrystalline cellulose, titanium dioxide (E171), quinoline yellow(E172), magnesium stearate.

HYPERIL 20 mg tablets

Each tablet contains 20 mg anhydrous lisinopril (as lisinopril dihydrate). The other ingredients are: mannitol, colloidal silicon dioxide, calcium hydrogen phosphate dihydrate, pregelatinized starch, magnesium stearate.

What HYPERIL looks like and contents of the pack

The 5 mg tablets are light pink, round tablets with a scoreline on one side. They are supplied as PVC / PVDC Aluminium blister packs in a carton box in pack sizes of 30(3 x 10) tablets.

The 10 mg tablets are light yellow, round tablets with a scoreline on one side. They are supplied as PVC / PVDC Aluminium blister packs in a carton box in pack sizes of 30(3 x 10) tablets.

The 20 mg tablets are white, round tablets with a scoreline on one side. They are supplied as PVC / PVDC Aluminium blister packs in a carton box in pack sizes of 30(3 x 10) tablets.

Marketing Authorisation Holder and Manufacturer:

ZADA Pharmaceuticals d.o.o.
Donji Bistarac without number
75300 Lukavac, Bosnia and Herzegovina.

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