

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Skopryl plus 20 mg/12.5 mg tablets

Lisinopril/Hydrochlorothiazide

**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 or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their sign of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

#### **What is in this leaflet:**

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

1. **WHAT SKOPRYL PLUS IS AND WHAT IT IS USED FOR**
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Skopryl plus are tablets containing the ingredients lisinopril and hydrochlorothiazide and are used to treat high blood pressure. If high blood pressure is left uncontrolled it can increase the risk of heart disease or a stroke.

Lisinopril belongs to a group of medicines called angiotensin-converting enzyme inhibitors (ACE inhibitors). It works by widening your blood vessels which helps to reduce raised blood pressure.

Hydrochlorothiazide belongs to the group of drugs called diuretics (water tablets). It increases the amount of urine you make which causes your body to get rid of extra water.

Skopryl plus works by lowering your blood pressure which reduces the risk of heart disease or a stroke.

## 2. BEFORE YOU TAKE SKOPRYL PLUS

### Do not take Skopryl plus if you:

- Are allergic (hypersensitive) to the active substances or any of the other ingredients of Skopryl plus.
- Have previously been treated with medicine called an ACE inhibitor and have had allergic reactions with swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing (a condition called angioedema).
- Have been diagnosed with angioedema that you inherited from a parent or angioedema from an unknown cause.
- Are allergic to any sulphonamide-derived drugs which include some antibiotics and diabetic medicines (ask your doctor if you are not sure).
- Suffer from an inability to pass water (anuria).
- Suffer from severe liver or kidney impairment.
- If you are more than 3 months pregnant. (It is also better to avoid Skopryl plus in early pregnancy - see pregnancy section.).

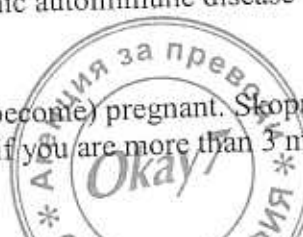
Skopryl plus is not for use in children.

### Take special care with Skopryl plus

Please tell your doctor if you:

- Have or have had any allergies or asthma.
- Suffer from liver, kidney or heart disease.
- Have a specific type of heart and lung disease called aortic stenosis.
- Have been told you have abnormal levels of the following natural body chemicals: potassium, calcium, urea, creatinine, uric acid, cholesterol or triglycerides.
- Are undergoing dialysis.
- Have recently suffered from excessive vomiting or diarrhoea.
- Suffer from sugar diabetes.
- Have gout (swollen painful joints caused by a build up of uric acid).
- Have systemic lupus erythematosus or SLE (a chronic autoimmune disease that can affect any part of the body).

You must tell your doctor if you think you are (or might become) pregnant. Skopryl plus 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 and breast-feeding section).

You should tell your doctor if you are on a salt-restrictive diet, if you are taking potassium supplements, potassium-sparing agents or potassium-containing salt substitutes.

If you are about to have a treatment called LDL apheresis, which is the removal of cholesterol from your bloodstream by a machine, you should tell the doctor who is treating you that you are taking Skopryl plus.

Please note that when you are on this medicine it may affect any tests your doctor may perform on blood or urine samples. Please remind your doctor you are taking Skopryl plus H if ever they want to carry out such a test.

Before surgery and anaesthesia (even at the dentist's) you should tell the doctor or dentist that you are taking Skopryl plus as there may be a sudden fall in blood pressure.

If you are about to have desensitisation treatment, that is treatment to reduce the effects of an allergy to bee or wasp stings, you should tell the doctor who is treating you that you are taking Skopryl plus

### **Taking other medicines**

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

It is especially important for your doctor to know if you are taking:

- Insulin or tablets to lower blood sugar (medicines for the treatment of diabetes).
- Diuretics (water tablets) and other medicines used to reduce blood pressure.
- Medicines for treatment of mental disorders such as lithium, antipsychotics or tricyclic antidepressives.
- Tubocurarine (a muscle relaxant used in anaesthesia).
- Non-steroidal anti-inflammatory drugs (NSAID).
- Allopurinol used for the treatment of gout.
- Medicines for the treatment of cancer.
- Immunosuppressive agents such as ciclosporin used following transplant surgery or for treatment of disorders such as rheumatoid arthritis.
- Steroids to treat various conditions including rheumatism, arthritis, allergic conditions, certain skin diseases, asthma or a blood disorder.
- Cardiac glycosides used to treat heart conditions such as digoxin.
- Sotalol or procainamide used to treat abnormal heart rhythms.
- Trimethoprim (medicine used for treatment of infections).
- Medicines such as ephedrine, noradrenaline or epinephrine (adrenaline) used for the treatment of hypertension, shock, cardiac failure, asthma or allergies.
- Colestyramine, colestipol or lovastatin which are used to treat hyperlipidaemia (high levels of cholesterol in the blood).
- ACTH to test whether your adrenal glands are working properly.
- Potassium supplements, potassium-sparing agents such as amiloride or potassium-containing salt substitutes.
- Injectable gold salts (used for treatment of rheumatoid arthritis)
- Calcium salts

### **Taking Skopryl plus with food and drink**

You may take this medicine with or without food. The effects of medicines used to reduce blood pressure can be increased when taken with alcohol and may cause dizziness or light-headedness. If you are concerned about how much alcohol you can drink while you are taking Skopryl plus H discuss this with your doctor.

### **Pregnancy and breast-feeding**

Ask your doctor or pharmacist for advice before taking any 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 Skopryl plus H before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Skopryl plus H. Skopryl plus 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 breast-feeding or about to start breast-feeding. Skopryl plus 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**

Your tablets are unlikely to affect your ability to drive a car or operate machinery. However, you should not perform such tasks, which need special attention, until you know how your medicine affects you. If you feel tired or dizzy do not drive or operate machinery until you have discussed this with your doctor.

### **3. HOW TO TAKE SKOPRYL PLUS**

Always take Skopryl plus exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual dose is one tablet taken once a day. If necessary, the dosage may be increased to 2 tablets, taken once daily.

Be especially careful when you take your first dose or if your dose is increased. Let your doctor know as soon as possible if you feel any dizziness or light-headedness. If you are already taking diuretics your doctor may tell you to reduce the dose of the diuretic, or even tell you to stop taking them, before you start to take Skopryl plus.

The effect of Skopryl plus tablets lasts 24 hours so you only need to take the tablets once a day. Skopryl plus can be taken at any time of the day before, during, or after a meal. Choose a time that is convenient for you and take your tablet at this time every day. This will help you remember whether you have taken your tablet for that day.

Skopryl plus is not for use in children.

Keep taking your tablets until your doctor tells you to stop.

#### **If you take more Skopryl plus than you should**

If you take more Skopryl plus than you should, see your doctor as soon as possible.



The most likely symptoms of overdose would be a feeling of light-headedness or dizziness due to a drop in blood pressure.

#### **If you forget to take Skopryl plus**

Do not take a double dose to make up for a forgotten dose, just take the next day's tablet when it is due.

#### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Skopryl plus can cause side effects, although not everybody gets them. Skopryl plus contains two medicines: lisinopril and hydrochlorothiazide. The following side effects have been seen with these individual medicines. This means they could also happen with Skopryl plus.

Your doctor may take blood samples from time to time to check whether Skopryl plus has had any effect on your blood.

##### **Possible side effects with lisinopril**

**Severe allergic reactions** (rare, may affect up to 1 in 1,000 people)

If you have a severe allergic reaction, **stop taking Skopryl plus and see a doctor immediately.**

The signs may include sudden onset of:

- Swelling of your face, lips, tongue or throat.
- Severe or sudden swelling of your hands, feet or ankles.
- Difficulty breathing.
- Severe itching of the skin (with raised lumps).

**Severe liver problems** (very rare, may affect up to 1 in 10,000 people)

The signs may include:

- Yellowing of your skin or eyes, dark coloured urine or a loss of appetite.

If this happens to you, **see a doctor immediately.**

##### **Other possible side effects:**

**Common (may affect up to 1 in 10 people)**

- Headache.
- Feeling dizzy or light-headed, especially if you stand up quickly.
- Fainting.
- Diarrhoea.
- Being sick (vomiting).
- Cough.
- Kidney problems (shown in a blood test).

**Uncommon (may affect up to 1 in 100 people)**

- Mood changes including feeling depressed.
- Tingling feeling such as 'pins and needles'.
- Spinning feeling (vertigo).
- Changes in the way things taste.
- Difficulty in sleeping.

- Heart attack or stroke.
- Unusual heartbeat.
- Change of colour in your fingers or toes.
- Runny nose.
- Feeling sick (nausea).
- Stomach pain and indigestion.
- Changes in blood tests that check how the liver is working.
- Rash.
- Itching.
- Being unable to get an erection (impotence).
- Feeling weak.
- Feeling tired.
- Increased levels of certain substances in your blood (urea, creatinine or potassium).

**Rare (may affect up to 1 in 1,000 people)**

- Changes to some of the cells or other parts of your blood. The signs may include feeling tired and pale skin.
- Feeling confused.
- Dry mouth.
- Skin rash with dark red, raised, itchy bumps (hives).
- Hair loss (alopecia).
- Psoriasis (a skin problem).
- Kidney failure.
- Enlarged breasts in men.
- Low levels of sodium in the blood, which may cause weakness, tiredness, headache, feeling sick, being sick (vomiting) and cramps.

**Very rare (may affect up to 1 in 10,000 people)**

- Problems with your bone marrow or a reduced number of blood cells and/or platelets in your blood. You may notice tiredness, an infection (which may be serious), fever, feeling breathless or that you bruise or bleed more easily.
- Swollen glands (lymph nodes).
- Increased immune response (autoimmune disease).
- Low levels of sugar in your blood (hypoglycaemia). The signs may include feeling hungry or weak, sweating and a fast heartbeat.
- Suddenly feeling wheezy or short of breath (bronchospasm).
- Lung inflammation (which may make you feel breathless).
- Sinusitis (a feeling of pain and fullness behind your cheeks and eyes).
- Eosinophilic pneumonia. The signs include a combination of the following: sinusitis, feeling like you have flu, feeling more and more breathless, pain in the area of your stomach or gut, skin rash, a feeling of 'pins and needles' or numbness of your arms or legs.
- Inflammation of the pancreas. This causes moderate to severe pain in the stomach.
- Swelling of the lining of the gut. This may cause sudden stomach pain, diarrhoea or make you be sick (vomit).
- Sweating.
- Severe skin disorder or rash. The symptoms include redness, blistering and peeling of the skin which may develop quickly and may include blistering in the mouth and nose.
- Passing less water (urine) than normal or passing no water.



**Possible side effects with hydrochlorothiazide (frequency cannot be estimated from the available data)**

- Inflammation of a salivary gland.
- A reduced number of blood cells and/or platelets in your blood. You may notice tiredness, an infection (which may be serious), fever, feeling breathless or that you bruise or bleed more easily.
- Loss of appetite.
- An increase in the amount of sugar (glucose) in your blood.
- Sugar in your urine.
- An increase in the amount of uric acid in your blood.
- Altered levels of substances in your blood (for example low sodium and potassium). You may notice muscle weakness, thirst, 'pins and needles', cramps or feeling sick.
- Raised levels of fats in your blood (including cholesterol) or uric acid.
- Feeling restless.
- Depression.
- Difficulty sleeping.
- Tingling feelings such as 'pins and needles'.
- Feeling light headed.
- Changes to your vision that can make things look yellow.
- Problems with your sight for a short time.
- A spinning feeling (vertigo).
- Feeling faint (especially when standing up).
- Damage to blood vessels causing red or purple spots in the skin.
- Difficulty breathing. You may feel breathless if your lungs get inflamed or have fluid on them.
- Stomach irritation.
- Diarrhoea.
- Constipation.
- Inflammation of the pancreas. This causes moderate to severe pain in the stomach.
- Yellowing of your skin or the whites of your eyes (jaundice).
- Skin problems including rash caused by sensitivity to sunlight, rash, a severe rash that develops quickly with blistering or peeling of the skin and possibly blistering in the mouth, worsening of existing lupus erythematosus-like reactions or appearance of unusual skin reactions.
- Allergic reactions.
- Muscle cramps and muscle weakness.
- Kidney problems which may be severe (shown in blood tests).
- Fever.
- Weakness.

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 SKOPRYL PLUS**

This medicine does not require any special storage conditions.



Keep this medicine out of the sight and reach of children.  
Do not use this medicine after the expiry date which is stated on the carton after Expiry date. The expiry date refers to the last day of that month.  
Do not use this medicine if you notice that the pack is damaged.  
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. CONTENT OF THE PACK AND OTHER INFORMATION

### What Skopryl plus contains

The active substances in Skopryl plus 20 mg/12.5 mg tablets are lisinopril and hydrochlorothiazide. Each tablet contains 20 mg of lisinopril (as dihydrate) and 12.5 mg of hydrochlorothiazide.

The other ingredients are mannitol, calcium hydrogen phosphate anhydrous, maize starch, pregelatinised maize starch, povidone, magnesium stearate and Pigment Iron Oxide Brown 75E 172 (contains iron oxide black and iron oxide red).

### What Skopryl plus looks like and contents of the pack

Skopryl plus 20 mg/12.5 mg tablets are pale brownish-violet round biconvex tablets with bisection line on one side. The score line is not intended for breaking the tablet.

The Skopryl plus 20 mg/12.5 mg tablets are available in pack size of 30 tablets.

### Marketing Authorisation Holder and Manufacturer responsible for batch release:

Alkaloid – INT d.o.o.  
Šlandrova ulica 4  
1231 Ljubljana-Črnuče  
Slovenia.

This medicinal product is authorised in the Member States of the EEA under the following names:

Bulgaria	Skopryl plus 20 mg/12.5 mg tablets
Czech Republic	Skopryl plus H 20 mg/12.5 mg tablets
Hungary	Skopryl plus 20 mg/12.5 mg tablets
Poland	Skopryl plus 20 mg/12.5 mg tablets
Slovak Republic	Skopryl plus 20 mg/12.5 mg tablets
Slovenia	Skopryl HCT 20 mg/12.5 mg tablets
Romania	Skopryl plus 20 mg/12.5 mg tablets

This leaflet was last revised in

Round seal of Bulgarian Drug agency