# INSTRUCTIOS FOR USE

**SKOPRYL® 10 mg tablets**
**SKOPRYL® 20 mg tablets**
**lisinoprilum**

**Please, read the instructions before use!**
-Save the instructions – you may wish to read it later again.
-If after reading you have any questions, ask your doctor or pharmacist.
-This medicine was prescribed personally to you and cannot be given to any other person for whom it could be harmful, although they have disease blemishes, similar to yours.
-If any adverse reaction becomes serious or if you notice any adverse reaction, not mentioned in these instructions, inform your doctor or pharmacist.

**Instructions include:**



## 1. WHAT IS MEDICINE SKOPRYL AND FOR WHICH PURPOSE IT IS USED?

The medicine Skopryl contains the active substance lisinopril, which is the inhibitor of the angiotensin convertase (ACE inhibitor) and belongs to medicines for lowering the blood pressure and facilitates blood pumping for the heart in all parts of body. It can be used independently or in combination with other medicines.

The medicine Skopryl is used for treatment of:
- increased blood pressure (hypertension),
- all levels of heart failure where your heart does not pump blood through your body as it should,
- acute heart attack,
- renal diseases (diabetic nephropath) in patients with diabetes, depending on insulin and having normal blood pressure, and in patients with increased blood pressure and diabetes, not depending on insulin.

The medicine Skopryl is in children and adolescents (aged from 6 to 16 years) recommended only for treatment of high blood pressure (hypertension).

## 2. WHAT YOU SHOULD KNOW BEFORE TAKING SKOPRYL

**Do not take this medicine if:**
- you are allergic (hypersensitive to) to lisonipril, other ACE inhibitors or any ingredient of the medicine Skopryl,
- if you were treated any time before with the medicine from the same group as lisopril is (ACE inhibitors), or had any allergic reaction with difficulty swallowing and breathing, with swollen hands, feet, ankles, face, lips, tongue or throat (angioedema),
- if you know about any cases of angioedema that occurred in your family or you have had angioedema in any other circumstances,

- if you are pregnant for more than three months (it is better to avoid using the medicine Skopryl in the earlier pregnancy period - see chapter Pregnancy and breastfeeding).

**Be especially careful when taking the medicine Skopryl**

- if you are dehydrated due to treatment with medicines that increase water excretion (diuretics), dialysis, limitation of salt in the nutrition, or because you had diarrhoea or you vomited, since it is more probable in this case that after starting treatment with lisonopril blood pressure will excessively lower and you will feel that as a vertigo or fainting,
- if you have a narrowed aorta valve (aorta stenosis) or a narrowed cardiac valve (mitral valve stenosis), thickening of the heart muscle (hypertrophic cardiomyopathy),
- if you have congestive heart failure,
- if you have ischemic heart disease, cardiovascular disease or acute heart attack,
- if you have renal disease or narrowed one or both renal arteries leading into kidneys,
- if you have liver disease,
- if you have any problems with veins (for example peripheral vascular disease or generalized hardening of the arteries or collagen vascular disease),
- if you have diabetes,
- if you take medicines that increase excretion of water (diuretics), potassium substitutes or salts,
- if you have a low blood pressure (manifested as vertigo or you have a feeling that you are going to faint, especially while rising up),
- if you breastfeed,
- if you have high levels of cholesterol values and you are treated with the so-called »aphaeresis LDL«,
- if you are member of a black-race, since the medicine Skopryl is in this case less effective and you may develop an adverse reaction angioedema (severe allergic reaction),
- if you are subject to or you have a foreseen desensibilization treatment against allergy, for example against insects' stings. Desensibilization treatment lowers the allergy effects (for example to stings of bees or wasps), however in some cases it may cause severe allergic reactions, if you take ACE inhibitors during desensibilization treatment,
- if you have a foreseen surgical procedure (including dental surgical operation), you should tell your doctor or dentist that you take the medicine Skopryl. The medicine Skopryl in combination with local and general anaesthetics may cause blood pressure drop soon after taking the tablets.

You must tell the doctor if you think that you are pregnant (or you might get pregnant). Administration of the medicine Skopryl in the early pregnancy period is not recommended, while after the third month of pregnancy is not allowed, since in this period the medicine can be seriously harmful for your child (see chapter Pregnancy and breastfeeding).

**Stop taking the medicine immediately and visit your doctor,** if the following allergic reactions develop:

- difficulty breathing together with swollen face, lips, tongue and/or throat or without swelling,
- swollen face, lips, tongue and/or throat that may cause difficulty swallowing,
- severe itching of skin (with a blistering or any other rash),
- if your palms, feet or ankles are swollen and they itch you.

**Be especially careful when taking the medicine Skopryl for the first time**

The medicine Skopryl may cause higher reduction of blood pressure. You may feel that as vertigo or you will have a feeling that you are going to faint. In this case it might help that you lie down. If you are worried, you should consult your doctor as soon as possible.

**Administration of other medicines**
Inform your doctor of pharmacist if you take or you have recently taken any medicine, also obtained without prescription. Some medicines have an influence on the medicine Skopryl action and vice versa.

Tell the doctor if you take:
- diuretics (medicines which increase the urine formation), including those which retain potassium,
- other medicines for treatment of increased blood pressure (antihypertensives),
- nonsteroidal anti-inflammatory medicines (NSAID) such as indomethacin or high doses of acetylsalicylic acid (more than 3 g per day), used for treatment of arthritis or pains in muscles,
- medicines that contain gold salts and are used in injections (for example sodium aurothiomalate used for treatment of arthritis),
- medicines for treatment of mental disorders, for example lithium (since frequent verification of lithium concentration in blood is needed at necessary concomitant treatment),
- antipsychotics or three-cyclic antidepressants,
- tablets with potassium or salt substitutes containing potassium,
- medicines for treatment of diabetes such as insulin or those that are taken for decreasing blood sugar;
- medicines stimulating the central nervous system (simpatico-mimetics). Among them there are ephedrine, pseudoephedrine and salbutamol that can be found in some decongestives, medicines against cough/cold and medicines against asthma,
- medicines that inhibits the body immune response (immunosuppressives), allopurinol (for treatment of gout) or procainamide (against heart rhythm disorders).

**Administration of Skopryl with food and drink:**
You can take the tablets before meal, during it or after it.

**Pregnancy and breastfeeding**
Consult your doctor or pharmacist before taking any medicine.
**Pregnancy**
You must tell your doctor if you think you are pregnant (or you may get pregnant).
Administration of the medicine Skopryl in the early pregnancy period is not recommended, while after the third month of pregnancy is not allowed, since in this period the medicine can be seriously harmful for your child (see chapter Pregnancy and breastfeeding). Doctor will normally advise you to stop taking the medicine Skopryl before you get pregnant or immediately when you find out that you are pregnant or he/she will advise you to take any other medicine instead of Skopryl.
**Breastfeeding**
Inform your doctor if you breastfeed or you intend to breastfeed.
If you breastfeed, it is not recommended to take the medicine Skopryl. If you intend to breastfeed, especially a new born baby or premature new born, the doctor may prescribe you treatment with another medicine.

**Effects on the ability to drive and use machines**
During treatment with the medicine Skopryl dizziness or tiredness may sometimes develop. Do not drive or use the vehicles or machine and do not perform activities requiring special attention if the medicine has such an influence on you.

## 3. HOW TO TAKE THE MEDICINE SKOPRYL

When taking Skopryl, strictly take in consideration the instructions given by your doctor. If in doubt, consult a doctor or a pharmacist.
The doctor will told you the dose level, the frequency of medicine administration and how long the treatment will last. Dosing is adapted to each individual patient and it is important that you take the medicine as prescribed by the doctor. Your initial dose and the dose for long-term use depend on your medical condition and on the fact if you take any other medicines.

Skopryl tablets are designed for oral use.
Take them before meal, during it or after it.

**Usual dosing is as follows:**

**Raised blood pressure**
Adults
The recommended initial dose is 10 mg, once per day. The dose must be adapted according to lowering of blood pressure. Usual maintenance dose in the form of one dose amounts to 20 to 40 mg. Daily dose is increased in weekly intervals up to the highest, which is 80 mg once per day.
Due to narrowing of one or both renal arteries (renovascular hypertension), in patients with the raised blood pressure, the initial dose amounts to 5 mg or less once per day. Dosing is individual, usual maintenance dose is 20 mg once per day.
Children and adolescents (aged from 6 to 16 years)
The doctor will choose a dose suitable for a child. The dose depends on the child's body weight:

- For children weighting from 20 to 50 kg, usual initial dose is 2.5 mg once per day; this dose may be increased to a maximum of 20 mg once per day. For initial dose, which cannot be achieved with the medicine Skopryl, the doctor will prescribe you another medicine with the same active substance, but of different strength.
- For children weighting more than 50 kg, usual initial does is 5 mg once per day; this dose may be increased to a maximum of 40 mg once per day.

The use of lisonopril in children, under 6 years and/or in children having severe problems with kidneys is not recommended.

**Heart failure**
The recommended initial dose amounts to 2.5 to 5 mg once per day. Every two to four weeks the dose is gradually increased to all patients until usual effective single does is achieved (from 5 to 20 mg per day).

**Acute myocardial infarction**
The recommended initial dose for patients with systolic blood pressure above 120 mmHg is 5 mg once per day first two days after acute myocardial infarction. The recommended dose is 10 mg once per day for six weeks.
The recommended initial dose for patients with systolic blood pressure from 100 to 120 mmHg is 2.5 mg once per day first two days after acute myocardial infarction. The maintenance dose is 5 mg once per day for six weeks. If during treatment systolic blood pressure decreases to less than 100 mmHg, the maintenance dose must be lowered to 2.5 mg once per day. If the blood pressure continues to remain low (systolic pressure is for more than one hour less than 90 mmHg), the use of lisinopril should be stopped.

**Renal disease (diabetic nephropath) in patients with diabetes who are dependent on insulin, but they have normal blood pressure, and in patients with increased blood pressure and diabetes which does not depend on insulin**
The recommended initial does is 2.5 mg once per day, which must be adapted to each patient separately during maintenance treatment, so that the blood pressure will be regulated.

**Dose adaptation in patients with renal impairment**
If you are a patient with renal impairment the doctor might prescribe you a lower dose of lisinopril.

**Elderly**
If you are elderly, your doctor will prescribe you a lower dose.

**Children and adolescents (aged from 6 to 16 years)**
The doctor will prescribe to your child a lower initial dose and increase the interval between individual doses.

**If you think that the effect of the medicine is too strong or too weak, consult your doctor or pharmacist.**

**If you have taken a higher dose of Skopryl than allowed**
If you have taken higher dose of medicine Skopryl than allowed, immediately consult your doctor or pharmacist.
The most significant symptom of excessive dosing of lisonopril is excessive lowering of blood pressure. The consequence of this may be dizziness and vertigo. Increased potassium concentration in blood (hypercalcemia), lowered sodium concentration in blood (hyponatremia), impaired kidney function and also acute renal failure may occur.
Treatment is symptomatic and functioning of vital organs should be ensured. The patient's stomach should be pumped (gastric lavage), an activated carbon should be given to him/her and dehydration, electrolyte imbalance and lowering of blood pressure should be corrected. There is no specific antitoxic product.
Lisinopril is removed from the organism with hemodialysis.

**If you have forgotten to take the medicine Skopryl**
Do not take a double dose to make up for a forgotten dose. Continue with administration according to usual schedule.

**If you have stopped taking the medicine Skopryl**
Do not stop taking tablets if you feel well, unless your doctor tells you to.

**If you have any additional questions on medicine administration, consult a doctor or a pharmacist.**

## 4. POSSIBLE UNDESIRABLE EFFECTS

As in administration of other medicines also in administration of Skopryl undesired effects occur, but not in all patients.

**Common undesired effects** (they may occur at up to 1 patient among 10 patients):
- headache,
- dizziness and feeling that you are going to faint, especially in fast raising up,
- cough,
- diarrhoea,

- vomiting,
- kidney malfunction (it manifests in blood testing).

**Uncommon undesired effects** (they occur at up to 1 patient among 100 patients):
- changes in mood,
- paresthesia,
- vertigo,
- taste disturbance,
- sleep disturbance,
- heart attack or stroke,
- discomfort at fast and strong heart beat (palpitation),
- fast heart beat (tachycardia),
- disturbance in functioning of arteries and arterioles, which manifests with periodic white finger attacks, especially on hands, sometimes also of ears and nose, accompanied by paresthesias and pains, while the attack is caused by cold and/or psychic shocks (Raynaud phenomenon),
- runny nose,
- nausea,
- abdominal pain,
- indigestion,
- rash,
- itching,
- hypersensitivity reaction manifesting in the form of swollen face, limbs, lips, tongue and throat,
- incapability to achieve erection,
- feeling of tiredness or weakness,
- blood tests showing changes in the way your liver and kidneys work.

**Rare undesired effects** (they occur at up to 1 patient among 1,000 patients):
- lowered concentration of red pigment in blood - haemoglobin in blood and lowered volume of red cells in blood,
- confusion,
- dry mouth,
- hives,
- hair loss,
- psoriasis,
- acute renal failure,
- enlargement of the male breasts (gynecomastia),
- lowered sodium level in blood which may be manifested with tiredness, headache, nausea and vomiting.

**Very rare undesired effects** (they can occur at up to 1 among 10,000 patients):
- blood disorders,
- disease of the lymph node,
- disease due to immune response against its own tissues (autoimmune disease),
- allergic reaction in the form of circular accumulation of fluid in intercellular spaces of the subcutaneous tissue body (angioneurotic oedema),
- low sugar levels in blood (hypoglycemia), whose symptoms may include feeling hungry, weakness, sweating and fast heart beat),
- constriction of bronchi (bronchospasm), resulting in difficulty breathing,
- sinusitis, which manifests with the pain in paranasal cavities,

- inflammation of the lung, which manifests with cough, feeling of shortness of breath and high fever,
- excess fluid in intercellular spaces in intestines,
- inflammation of the pancreas causing moderate to severe abdominal pain, nausea and vomiting,
- inflammation of the liver which may cause loss of appetite, yellowish pigmentation of the skin and/or eyes,
- jaundice (yellowish pigmentation of the skin and/or eyes),
- liver failure,
- excessive sweating,
- serious skin changes (symptoms including skin redness, blistering, skin flaking),
- lowered or discontinued discharge of urine.

**Unknown incidence** (incidence cannot be estimated from the available data):
- depression symptoms,
- faint.

**Paediatric patients**
The undesirable effects in children and adolescents are similar as in adults.

**If any undesirable effect become serious or you notice any undesirable effect, not mentioned in these instructions, inform your doctor or pharmacist!**

## 5. STORAGE OF SKOPRYL

**Medicine must be stored out of reach of children!**

No special instructions are needed for storage of the medicine.

Skopryl should not be used after the expiry date indicated on the packaging. The expiry date relates to the last day of the given month.

Do not use the medicine Skopryl if you notice any damages or change of colour of the tablets.

The medicine should not be disposed in waste waters or in domestic waste. Consult your pharmacist about the way of disposal of medicinal product that you do not need any more. Such actions help to protect the environment.

## 6. ADDITIONAL INFORMATIOn

**What does Skopryl contain**
- The active substance is lisinopril.

Skopryl 10 mg tablets:
One tablet contains 10 mg of lisinopril in the form of 10.89 mg lisinopril dhydrate.
Skopryl 20 mg tablets:
One tablet contains 20 mg of lisinopril in the form of 21.78 mg lisinopril dihydrate
- Excipients are:

Skopryl 10 mg tablets:
mannitol, calcium hydrogen phosphate, maize starch, pregelanitinised starch, yellow ferrous oxide (E172), magnesium stearate and povidone.
Skopryl 20 mg tablets :

mannitol, calcium hydrogen phosphate, maize starch, pregelanitinised starch, yellow ferrous oxide (E172), red ferrous oxide (E172), magnesium stearate and povidon.e

**Nature and contents of the package of the medicine Skopryl**
Skopryl 10 mg tablets:
Pale yellow, round, biconvex tablets with scoring on one side. The tablet can be divided into two equal halves.
Box with 30 tablets (3 x 10 tablets in a blister). Blister Al/PVC film.
Box with 90 tablets (9 x 10 tablets in a blister). Blister Al/PVC film.
Skopryl 20 mg tablets:
Pale pink, round, biconvex tablets with scoring on one side. The tablet can be divided into two equal halves.
Box with 30 tablets (3 x 10 tablets in a blister). Blister Al/PVC film.
Box with 90 tablets (9 x 10 tablets in a blister). Blister Al/PVC film.

**General classification for supply of the medicine:**
The medicine is available on prescription only.

**Marketing authorization holder and manufacturer:**
ALKALOID-INT d.o.o.,
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1231 Ljubljana-Črnuče,
R Slovenija
Tel.: 01 - 300 42 90
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**For any further information about this medicine you may refer to the representation office of the marketing authorization holder.**

**Instructions were approved**: on 29 May 2012.