PACKAGE LEAFLET: INFORMATION FOR THE USER

PROPRANOLOL LEK

40 mg Tablets

PROPRANOLOL HYDROCHLORIDE

• 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 PROPRANOLOL LEK IS AND WHAT IT IS USED FOR

Propranolol is a medicine from the group of beta-adrenergic blockers, which are used for controlling the blood pressure and reducing damage to the heart. All beta-adrenergic blocking agents act by blocking the influence of the sympathetic part of the vegetative nervous system on the body tissues and organs. Specifically, these medicinal ingredients occupy places on cell membranes (receptors) by which the sympathetic nervous system acts on the body.
Due to the blockade of beta-adrenergic receptors which are located in the blood vessel system, it reduces the heart rate (heart rate), the ability of the heart muscle contraction and stops the expansion of blood vessels, which is a result of the sympathetic nervous system. Because propranolol is a non-selective beta-adrenergic blocking agent, it does not hinder the effect of the sympathetic nervous system only in the vascular system, but also in other tissues and organs. Therefore, the additional side effects are possible (see section "Take special care with Propranolol Lek" and "Side Effects").

Propranolol Lek is used for the treatment of:

- high blood pressure

- angina pectoris (a heart disorder with weight, pressure, chest pain)
- condition following a heart attack (preventive treatment complications, and development of re-infarction)
- cardiac arrhythmia (heart rhythm disorders)
- migraine prevention of attacks (intense unilateral headache)
- essential tremor (shaking rhythmic movements)
- hypertrophic obstructive cardiomyopathy (disease of the heart muscle where a portion of the heart muscle thickened without any obvious cause and cause an obstacle in the flow of blood from the heart)
- increased activity of the thyroid - as an adjunct therapy
- pheochromocytoma - high blood pressure caused by tumors usually near the kidney (only with proper treatment), and for
- prevention of bleeding in the digestive tract due to portal hypertension (high blood pressure in the liver) and varicose veins of the esophagus (prevention of bleeding in the esophagus caused by high blood pressure in the liver).

2. BEFORE YOU TAKE PROPRANOLOL LEK

Do not take Propranolol Lek:

- if you are allergic to propranolol or any of the other ingredients
- if you suffer from severe heart problems that can cause shortness of breath or swelling of the joints, and do not respond to treatment
- If you have a very slow heartbeat or have difficult disorders of implementation of the stimulus (ask your doctor about this condition)
- if you have sick sinus syndrome (a group of irregular heart beat-arrhythmia)
- If you have very low blood pressure
- If you have a specific form of angina pectoris, chest pain (variant or Prinzmetal angina) ask your doctor to explain its characteristics
- if you have or have had bronchial asthma or difficulty in breathing, wheezing (bronchospasm)
- If you have difficult disorders of peripheral blood flow
- If you are hypersensitive (allergic) to pollen
- If you have pheochromocytoma, which is not treated with alpha-adrenergic blocker
- if you have a metabolic acidosis (a condition that occurs when the body produces too much acid or the kidneys cannot remove enough acid from the body, which causes shortness of breath, confusion and fatigue) after prolonged starvation
- If you are taking monoamine oxidase (MAO) - a group of strong antidepressant medicines for treating depression (exception: MAO-3 inhibitors). If you are not sure whether you can start treatment with Propranolol Lek, consult your doctor.

Take special care with Propranolol Lek:

Talk to your doctor about any health problems you have or have had, and about any possible hypersensitivity reactions - allergies.

Warn your doctor if you have heart or lung disease, slowed heart rate, chest pain, arterial peripheral blood flow disorders, major health problems with liver or kidney, or if you receive other medicines to treat high blood pressure. In this case, the doctor may need to adjust the dose or medication you are already taking, or a dose of Propranolol Lek, or will opt for other means of treatment. If necessary, the doctor will alert you to signs of disease which you should pay special attention to.

In patients with diabetes Propranolol may mask some signs characteristic of recognition of hypoglycemia (a condition when blood sugar is lowered). Therefore tell your doctor if you have diabetes that is regulated with medicines.

The anesthesia given for major surgery during the treatment with propranolol may lower the blood pressure. Therefore, before any major surgery, tell your doctor that you are taking Propranolol Lek.

Propranolol may mask signs of hyperfunction of the thyroid gland. Warn your doctor if you are being treated for thyroid disease; you may require stricter control of the treatment.

In patients with a history or family history of psoriasis, Propranolol can be prescribed only after careful consideration of the risk-benefit relation.

Treatment with Propranolol Lek should never be suddenly discontinued. Treatment must always be stopped slowly, gradually; otherwise complications can occur, even very serious ones.

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.

Propranolol is commonly administered together with other medicines.
In patients with diabetes who are treated with tablets or insulin, propranolol can affect blood sugar levels, increase the frequency, severity and duration of hypoglycemia (low blood sugar condition), and conceal some of the characteristic signs of this condition (see section "Take special care with Propranolol Lek ").
Propranolol may increase the effect of some medicines used for the treatment of depression and psychiatric disorders (fluoxetine, tricyclic antidepressants, phenothiazines, haloperidol). Therefore, you should inform your doctor if you are taking such medicines.
The doctor also needs to know if you are taking other medicines to control high blood pressure or heart rhythm disorders (arrhythmias), or other medicines for treating heart disease.
Painkillers and rheumatism can reduce the effect of propranolol on blood pressure.
Concomitant treatment with propranolol and some anti-migraine medicines (against migraine) may increase the potential for adverse effects on peripheral blood vessels.
The effectiveness of treatment with propranolol can be affected by the concomitant use of medicines for ulcer disease of the stomach or duodenum (ulcer in the stomach or duodenum), and the substances that bind stomach acid.

Taking food and drink with PROPRANOLOL LEK

Propranolol Lek can be taken with food and consumption of alcoholic beverages during treatment with this medicine is not recommended.

Pregnancy and breastfeeding

Pregnancy
Ask your doctor or pharmacist for advice before taking any medicine.
Propranolol Lek should not be used during pregnancy unless the use is necessary.
Propranolol can damage the fetus in the mother's body, cause premature labor and cause complications in the heart and lungs of newborns.

Breastfeeding
Do not take the medicine if you are breast feeding, because this medicine is excreted through breast milk.

Children
Safety and efficacy of propranolol treatment in children have been proven. Closely follow the doctor's instructions regarding the dosage of the medicine.

Driving and using machines

Propranolol generally does not affect the ability to drive and use machines. However, we recommend caution, because in some patients, especially at the beginning of treatment, the medicine can cause drowsiness and / or fatigue.

Other warnings

Each tablet contains 0.11 g lactose. If you are taking medication according to the instructions for dosage, the highest daily dose taken will reach 1.1 g of lactose. The maximum daily dose amount of lactose does not exceed 5 g.

The medicine is not suitable for people with lactase deficiency, galactosemia and glucose / galactose malabsorption syndrome.

3. HOW TO TAKE PROPRANOLOL LEK

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.

Adults

High blood pressure
The usual initial daily dose is 40 mg (1 tablet) twice a day. The doctor may increase at weekly intervals based on patient response.

Most patients required daily dose of between 160 and 320 mg. Daily doses greater than 320 mg should be divided into three or four equal doses.

The most pronounced decrease in blood pressure may occur 2-4 weeks after starting treatment.

Angina pectoris
A starting dose of 40 mg twice or three times a day the doctor may increase for the same amount in weekly intervals with respect to the patient's response.

The corresponding response in angina pectoris is usually achieved by the doses of 120 - 240 mg / day.

It appears that the optimum average daily dose is 160 mg. In particular, refractory cases, satisfactory results are achieved with daily doses of 320-400 mg.

Heart rhythm disorders
With 10 to 40 mg three or four times daily the patient's response is achieved.

Condition after heart attack
Treatment starts between 5 and 21 days after a heart attack with an initial dose of 40 mg four times daily for the first 2 or 3 days. The patient can then take entire daily dose in two doses of 80 mg. Maximum daily dosage is between 180 and 240 mg. They can be administered as separate doses. The medicine should be taken for at least three years.

Migraine
The initial dose of 40 mg is taken twice or three times daily. The dose is then slowly increased until it causes a satisfactory termination of migraine attacks. The usual effective daily dose is from 80 to 160 mg.

Hypertrophic obstructive cardiomyopathy
With 10 to 40 mg three or four times daily the doctor typically requires that the patient's response is achieved.

Thyrotoxicosis
With 10 to 40 mg three or four times daily the doctor typically requires that the patient's response is achieved.

Essential tremor
The recommended starting dose of the medicine is 40 mg two or three times daily. The doctor may increase by the same amount at weekly intervals, depending on patient response. The desired response in essential tremor the doctor usually achieves with dose of 80-160 mg / day. In the elderly, a daily dose greater than 120 mg may result in a slow heart rate, fainting or difficulties in breathing and panting.

Pheochromocytoma

When the alpha-adrenergic blocking agent is introduced in the primary treatment, propranolol can be used as an additional drug to control tachycardia. Before surgery, propranolol is administered three days at a daily dose of 60 mg. For long-term treatment for inoperable pheochromocytoma a daily dosage of 30 mg usually suffices.

Portal hypertension
Propranolol is administered for the prevention of gastrointestinal bleeding due to portal hypertension and varicose veins in the esophagus, stomach or colon: the dosage is 40 mg twice daily. The dose is gradually increased until the resting heart rate decreases by about 25%. The maximum daily dose is 360 mg, and shall be divided into two doses.

Dosage for elderly patients

Propranolol should be used with caution. Therapy should begin by the lowest available dose. The optimal dose needs to be individually determined on the basis of therapeutic response.

Dosage in patients with renal impairment

Dose adjustment is not necessary, even in patients on dialysis.

Dosage in patients with hepatic impairment

Propranolol is almost completely metabolized in the liver. Therefore, it is necessary to carefully adjust the dose, and frequently control patients with hepatic impairment. The basic therapeutic principle of the individual titration of the dose until achieving the desired therapeutic response remains unchanged dosage.

Children

The dose will be determined individually. Doses are calculated based on body weight, and not body surface area. A typical daily dose of propranolol in children is from 2 to 4 mg / kg for oral administration. It is given in two equal doses.

High blood pressure
The recommended initial daily dosage for the treatment of high blood pressure in children is from 0.5 to 1 mg / kg; given in two equal doses. Daily doses for maintenance treatment are from 2 to 4 mg / kg; need to be divided into 2 to 4 equal doses. Dose was cautiously slowly titrated individually with regard to the therapeutic response of the patient and possible side effects.

Arrhythmias, pheochromocytoma, thyrotoxicosis
The dose is determined individually, taking into account the following general recommendations: from 0.25 to 0.50 mg / kg three or four times a day, depending on the clinical picture.

Migraine
Children under 12 years: 20 mg two or three times a day.
Children older than 12 years: adult dose.

Tetralogy of Fallot
For the symptomatic treatment of obstruction of right ventricular outflow tract, arrhythmia and stenocardia propranolol is dosed strictly individually. Framework recommended daily dose is 1 mg / kg, three to four times daily.

If you take more Propranolol Lek 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. The most likely signs of overdose include fainting and dizziness because of reduced blood pressure, and very slow heartbeat. There may be also loss of consciousness and convulsions.

If you forget to take Propranolol Lek
If you miss a dose, please do not compensate for it, but continue with the prescribed method of dosing.

If you stop taking Propranolol Lek
Do not stop taking PROPRANOLOL LEK unless your doctor advises you to do so.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Propranolol Lek may cause side effects.
Common (at 1 in 10 patients):

- A slow heart rate, worsening heart failure, low blood pressure which may be associated with fainting, in susceptible patients worsening heart block, rapid and irregular heartbeat
- Dizziness, slowness of thinking and feeling, dizziness, headache, difficulty in sleeping, anxiety, nervousness, decrease in mental concentration, reversible memory loss and catatonia (abnormal behavior that manifests itself with the stiffness of the body, slow thinking and feelings), vivid dreams, tingling or numbness in the hands or feet, loss of coordination
- A feeling of nausea, sickness, stomach pain, loss of appetite, bloating, milder diarrhea, constipation
- Reversible hair loss
- Fatigue, weakness, sweating
- Allergic skin reactions (redness, red rash, itching, generalized rash, rash like hives)
- Depression, confusion, hallucinations (when you see, hear or feel things that are not present)

Uncommon (more than 1 per 100 patients)

- Reduction in the number of platelets, which increases risk of bleeding or bruising, bleeding and / or bruising under the skin
- Loose eyelids, muscle weakness (myasthenia gravis)
- Abnormal vision, discharge from the eye with itching, redness and swelling, keratoconjunctivitis, reduced tear production (dry eye)
- Dry mouth

Rare (more than 1 per 1,000 patients)

- Visual disturbances, keratocysts-conjunctivitis

Very rare (more than 1 in 10,000 patients)

- Exacerbation of myasthenia gravis
- Arthropathy / difficulties with joint (monoarthritis and polyarthritis), muscle weakness or muscle spasms
- High blood sugar
- Cold and blue colored hands and feet, numb or cold fingers, leg pain, and nausea while walking
- The reduction or loss of libido

Unknown (cannot be estimated from the available data)

- Serious reduction in the number of white blood cells which increases the frequency of infections
- Difficulty breathing or audible high-pitched breathing (patients with COPD or asthma), sudden spasm (tightness / spasm) muscles of the pharynx, respiratory distress (breathing disorder)
- Psoriasis like skin reactions, exacerbation of psoriasis, acne-like skin changes face
- Reduced levels of sugar (glucose) in the blood, disorders of the lipid (fat), reduction of HDL cholesterol, an increase in triglyceride levels
- Serious allergic reaction which causes difficulty in breathing or dizziness, as well as an increase in body temperature and a sore throat, dry mouth and redness of the face

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

5. HOW TO STORE PROPRANOLOL LEK

Keep out of reach and sight of children.

Store the medicine at a temperature below 25° C.

Shelf life: 5 years
Propranolol Lek 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 Propranolol Lek contain?
The active substance is propranolol hydrochloride.

The other ingredients:
color E120 (red lipstick)
lactose monohydrate
microcrystalline cellulose
Anhy colloidal silica
magnesium stearate
talc

Pharmaceutical form:
Tablets

Pharmacotherapeutic group:
Beta-adrenergic blockers

What Propranolol Lek looks like and contents of the pack
Each tablet contains 40 mg of propranolol hydrochloride.

The tablets are pink, roan, round, flat with rounded edges, with cross-division on one side.

The boxes with bottles of 50 tablets containing 40 mg of propranolol hydrochloride.

Regime of dispensing
The medicine is issued on prescription.

Manufacturer
Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Slovenia