

PACKAGE LEAFLET: Information for the patient

PROPRANOLOL

Tablets – 40 mg

(Propranolol hydrochloride)

Read this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Propranolol is and what it is used for
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1. WHAT PROPRANOLOL IS AND WHAT IT IS USED FOR

Propranolol contains the active substance propranolol hydrochloride, which is part of the beta - blockers group.

Propranolol 40 mg tablets are used:

- in the management of hypertension;
- in the treatment of angina pectoris;
- in the prevention of other cardiac attacks, if you have passed one;
- in the treatment of hypertrophic cardiomyopathy;
- in the management of arrhythmias.

Propranolol tablets may also be used:

- in the prevention of severe headache (migraine);
- in the treatment of essential tremor;
- in the management of anxiety and anxiety tachycardia;
- as adjunctive treatment in the thyroid gland hyperactivity (thyrotoxicosis);
- in the treatment of hypertension caused by the tumour in the adrenal gland – phaeochromocytoma (only with an alpha-blocker);
- in the prevention of haemorrhage of the upper part of the gastrointestinal tract, in patients with hypertension in the liver and oesophageal varices.

2. BEFORE YOU TAKE PROPRANOLOL

Do not take Propranolol if:

- you are allergic (hypersensitive) to propranolol hydrochloride or to any of the excipients of this drug;
- you have suffered from bronchial asthma, bronchospasm or chronic obstructive bronchopneumopathy (BPCO);
- you have cardiovascular problems such as: uncontrolled heart failure, slow or irregular heart beats, cardiogenic shock, severe disorders of the peripheral arterial circulation, atrioventricular block of second and third degree, sick sinus syndrome, Prinzmetal angina (chest pain at rest and not during exercise);
- you have low blood pressure;
- you are at a fasting state for a long time or if your blood becomes too much acid (metabolic acidosis);
- you have hypertension caused by phaeochromocytoma, that is a tumour of the adrenal glands (except the case when you have treated it with an alpha-blocker);
- you are taking verapamil or diltiazem.

Take special care during the use of this drug

Before taking Propranolol tablets, tell your doctor if you:

- have passed an anaphylactic reaction, because the sensitivity to allergens may increase;
- have *Myasthenia gravis*;

- have atrioventricular block of first degree;
- have heart diseases caused by poor blood supply in this organ (ischemic heart diseases);
- have Raynaud's syndrome (disease that causes a cold sensitivity in the fingers) or continuous limping (disease caused by the narrowing of the arteries in the feet, that causes pain during walking and as a consequence limping);
- have renal or hepatic impairment (portal hypertension);
- have diabetes;
- have hypoglycemia or thyrotoxicosis, because their symptoms may be masked;
- have a skin disease called psoriasis, or if you have previously suffered from such disease;
- are going to do a test to verify the presence of glaucoma, because Propranolol may low the intraocular pressure;
- are in the period of pregnancy or breastfeeding.

Taking other medicines

Concomitant treatment with other drugs may affect or be affected by Propranolol. Please contact with your doctor or pharmacist if you are taking or have recently taken other drugs, including those obtained without a prescription. Do not forget to inform your doctor for the treatment with Propranolol if you have been given any other drug during treatment.

It is especially important that your doctor knows that you are taking or being treated with:

- diltiazem, nifedipine, verapamil or digoxin, that are used for the treatment of other cardiovascular diseases;
- clonidine, a drug that is used for the treatment of hypertension and migraine;
- reserpine;
- cimetidine or aluminium hydroxide, drugs that are used in case of hyperacidity in the stomach;
- hydralazine, a drug used for the treatment of hypertension;
- quinidine, dysopiramide, amiodarone, propafenone, flecainide, dronedarone that are used in the treatment of irregular heart beats;
- insulin, or other drugs that are used in the treatment of diabetes;
- theophyllin, that is used for the treatment of asthma;
- rifampicin, that is used for the treatment of tuberculosis;

- warfarin, that is used as an oral anticoagulant;
- rizatriptan and ergotamine derivatives, that are used in the treatment of migraine;
- adrenaline, that is used in the treatment of anaphylaxis;
- thyroxine;
- haloperidol;
- tricyclic antidepressants, barbiturates, phenothiazines, anaesthetics or inhibitors of prostaglandine synthesis.

Taking Propranolol tablets with food and drinks

Alcohol should not be consumed during treatment with Propranolol because it may change the way propranolol acts in the organism.

Pregnancy and breastfeeding

Ask for the advice of the pharmacist or of the doctor before taking this drug.

If you are pregnant, planning a pregnancy or breastfeeding, you should consult your doctor before you start the treatment with Propranolol.

Driving and using machines

This drug has not the tendency to influence the ability to drive and use machines. However, sometimes during treatment with Propranolol you may feel dizziness and fatigue. If this happens, do not drive or use other machineries and tell immediately your doctor.

Important information about some of the excipients of Propranolol

Propranolol tablets contain lactose. If you have an intolerance to some sugars, talk to your doctor before taking this medicine.

3. HOW TO TAKE PROPRANOLOL

Always take Propranolol as your doctor has told you. If you feel that the effects of Propranolol are too strong or too weak, talk to your doctor or pharmacist.

It is advised to take the tablets at the same time every day.

Propranolol tablets should be swallowed whole with a glass of water.

This medicine is for oral use only.

The dosage of Propranolol is as follows:

Adults

Hypertension: initial dose 80 mg daily. The maintenance dose is 160 - 320 mg daily.

Angina: initially 40 mg, 2 - 3 times daily; the maintenance dose is 120 - 240 mg daily.

Prophylaxis after myocardial infarction: 40 mg, 4 times daily for 2 - 3 days, then 80 mg twice daily, beginning from the 5th day to the 21st day after infarction.

Arrhythmia, Hypertrophic cardiomyopathy, Anxious tachycardia and Thyrotoxicosis: 10 -40 mg, 3 - 4 times daily.

Prophylaxis of migraine and Essential tremor: initially 40 mg 2 - 3 times daily; the maintenance dose is 80 - 160 mg daily.

Anxiety with symptoms such as palpitation, sweating, tremor: 40 mg once daily. If it is necessary, the dose may be increased to 40 mg, 3 times daily.

Phaeochromocytoma (to be used only with an alpha - blocker): 60 mg daily for 3 days before surgery or 30 mg daily, in patients who can not undergo surgery.

Prevention of the haemorrhage of the upper part of the gastrointestinal tract: initially 40 mg, twice daily; the dose may be increased up to 160 mg, twice daily when it is necessary.

Children

Children should not be treated with Propranolol, except under strict medical supervision.

For the treatment of cardiac rhythm disorders, phaeochromocytoma or thyrotoxicosis, the recommended dose for children is 0.25 - 0.5 mg / kg, 3 to 4 times daily.

For the prophylaxis of migraine, the dose is 20 mg 3 - 4 times daily. This dosage applies for children less than 12 years old. Children over 12 years old take the same dose as adults.

If you take more Propranolol than you should

If you take more Propranolol than you should, or if the children have taken this medicine incorrectly, please contact your doctor or call the hospital or emergency to get an opinion for the risk and an advice for the actions to be taken.

If you forget to take Propranolol

If you forget to take a dose (or more doses), take the next dose when it is time to take it usually.

Do not take a double dose (or higher) to make up for a forgotten dose (doses).

If you stop taking Propranolol

Propranolol should not be stopped immediately after a prolonged use, but gradually. Immediate withdrawal may result in angina, myocardial infarction, ventricular arrhythmia and death.

If you have further questions on the use of this medicinal product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all other medicines, Propranolol tablets may also cause side effects, although not everybody manifests them.

If any of the following side effects appears to you, stop the treatment with Propranolol and contact immediately your doctor:

- reduced heart beats, heart failure and atrioventricular block that worsens (the signs include breathing difficulty or swelling of the joints);
- dizziness and fainting;
- reduced peripheral blood circulation that develops foot cramps (Raynaud's syndrome);
- low level of sugar in the blood (hypoglycemia) in patients with diabetes or those who did not previously suffer from diabetes including the newborn, toddlers, children, elderly, people on haemodialysis and patients taking medicines for diabetes; may also happen in patients that are fasting or have been fasting recently or in people with a long-term liver disease (signs include weakening, headache, feeling hungry, visual disorders and mood changes);
- appearance of purple stains on the skin;
- muscle weakening and worsening of the muscle disease called *Myasthenia gravis*.

If any of the following side effects appears to you, contact immediately your doctor:

- bronchospasm;
- nightmares, fatigue and insomnia;
- headache;
- confusion;

- mood changes;
- memory loss;
- strange rumours and hallucinations;
- rash, bubbles on the skin, sneezing, chest tightening or collapse. These signs point to an allergic reaction to Propranolol tablets;
- cold and sting sensitivity in the fingers;
- excessive sweating;
- changes of plasmatic concentrations of triglycerides and cholesterol;
- feeling of being sick, abdominal pain, diarrhea, nausea, vomiting, constipation, dry mouth;
- pruritus, exacerbation of psoriasis;
- alopecia;
- impotence;
- seizure linked to low levels of sugar in the blood;
- changes in renal function (decrease in renal blood flow);
- joint pain;
- blood disorders (agranulocytosis);
- worsening of chest pains (angina pectoris);
- depression;
- dry eyes, visual changes, inflammation of the eyes (conjunctivitis).

If any of the side effects worsens, or if you notice side effects not listed in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE PROPRANOLOL

Keep out of the reach and sight of children!

Do not use Propranolol after the expiry date which is stated on the package.

Store below 25°C.

Store in the original packaging to protect it from light and humidity.

6. OTHER INFORMATION

What Propranolol contains

The active substance is Propranolol hydrochloride.

Each tablet contains 40 mg propranolol hydrochloride.

The excipients are: lactose monohydrate, microcrystalline cellulose, talc, magnesium stearate.

Content of the pack:

Carton box with 60 tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

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