PROLOL® Tablets

Patient package insert according to Pharmacists' Regulations (Preparations), 1986.

This medicine can be sold with a physician's prescription only.
Read this entire leaflet carefully before you start using this medicine.

Composition: Each tablet contains:
Prolol® 10:
Propranolol Hydrochloride 10mg
Prolol®40:
Propranolol Hydrochloride 40mg

Inactive ingredients:
Lactose monohydrate, cellulose microcrystalline, sodium starch glycolate, magnesium stearate, carmellose sodium, silica colloidal anhydrous.
Prolol® 10 also contains: orange lake E-110
Prolol® 40 also contains: red lake E -127, blue lake E-132

Therapeutic group: non-selective beta receptor blocker.

Therapeutic action: Prolol® belongs to a group of medicines called beta-adrenergic receptor blockers. This medicine has effects on the heart and blood circulation and also on other parts of the body. Prolol® is therefore used for many conditions, such as: treatment of hypertension, angina pectoris, for regulation of heart rhythm, tremor and prevention of migraine attacks.

When should this medicine not be used?

Do not use if you are aware of a hypersensitivity to propranolol or to any of the medicine's ingredients.
Do not use if you or anyone in your family are suffering or have suffered in the past from asthma and/or wheezing.
Do not use this medicine if you have suffered in the past from any of the following problems: uncontrolled heart failure, very slow or uneven heart beats, very low blood pressure, severe blood circulation disturbances, second or third degree heart block, a type of chest pain called Prinzmetal's angina (chest pain at rest).
Do not use in the following cases: untreated phaeochromocytoma (a tumor usually near the kidneys that might cause high blood pressure), metabolic acidosis (high level of acid in the blood), strict diet regimen or after fasting.
Do not use in patients prone to develop hypoglycemia (low blood sugar).

Do not use this medicine without consulting your physician before commencing treatment:

If you are pregnant, may be pregnant, or if you are breastfeeding; if you suffer or have suffered in the past from impaired function of: the respiratory system (e.g. shortness of breath, asthma), the heart (e.g.: treated heart failure, first degree heart block) and/or the vascular system, blood circulation disturbances, the liver (e.g. cirrhosis), the kidney/urinary tract, from an overactive thyroid gland, diabetes, depression, if you have allergic reactions (e.g.: to insect bites), if you consume alcohol frequently and in large quantities.
This medicine contains lactose, therefore, if you have been told by a physician in the past that you have an intolerance to certain sugars, consult your physician before starting treatment.

How will this medicine affect your daily life?

Use of this medicine does not usually cause dizziness or impair alertness. However, if you do experience weakness or dizziness, avoid driving a vehicle, operating dangerous machinery and engaging in any activity which requires alertness.
Children – should be cautioned against bicycle riding or playing near the road etc.

Warnings:

During treatment with this medicine the following tests should be performed: blood tests, blood pressure, liver, kidney and heart function.
If you are sensitive to any type of food or medicine, inform your physician before taking this medicine.
This medicine is used for the prevention of migraine attacks; therefore it should not be used after the attack has begun.
Please note: this medicine may reduce or prevent chest pains during physical exertion, therefore you should consult your physician regarding the level of physical activity you are allowed.
This medicine may cause sensitivity to cold weather. You should take care to dress warm and avoid prolonged exposure to cold.
If you are taking clonidine (for lowering blood pressure or for migraine) concomitantly with Prolol®, do not stop the treatment with clonidine unless instructed by your physician. The cessation of treatment with clonidine should be accompanied by explicit instructions from your physician.
If you are about to undergo any type of surgery (including dental surgery) or any anesthesia, inform the anesthesiologist or the medical staff that you are taking Prolol®.
If you need treatment for an allergic reaction, inform the physician that you are taking Prolol® .
Do not stop the treatment with Prolol® without consulting your physician; cessation of treatment with Prolol® should be carried out under medical supervision and in certain cases gradually.
If you consume alcohol frequently and in large quantities, consult your physician before taking the medicine, since alcohol may affect how the medicine works.

Drug interactions:

If you are taking any other medicines, including non-prescription medicines or herbal remedies, or if you have just completed treatment with another medicine, inform the attending physician in order to prevent hazards or inefficacy arising from drug interactions, especially medicines from the following groups: digoxin (for heart problems); clonidine (for lowering blood pressure or for migraine, see 'Warnings' section), antihypertensives (e.g. hydralazine), diuretics, medicines for chest pain (angina); medicines for heart rate control (disopyramide, lidocaine, propafenone, quinidine, amiodarone), medicines for heart diseases (e.g.: verapamil, diltiazem, nifedipine), heart stimulating medicines (such as adrenaline), warfarin (for thinning the blood), cold medicines and nasal decongestants, cimetidine (for stomach problems), medicines for the treatment of migraine (ergotamine, dihydroergotamine, rizatriptan), analgesics and anti-inflammatory medicines (e.g.: ibuprofen and indomethacin), chlorpromazine or thioridazine (for psychiatric disorders), rifampicin (for tuberculosis), insulin or oral antidiabetic medicines, anesthetics, theophylline or aminophylline (for asthma) or if you need treatment for an allergic reaction.

Side effects:

In addition to the desired effect of the medicine, some side effects may appear during treatment, such as:
Common side effects (appear in less than 1 in 10 people): slow or irregular pulse, cold hands and feet, numbness and spasms in the fingers followed by fever and pain (Raynaud's disease), sleep disturbances, nightmares, tiredness.
Uncommon side effects (appear in less than 1 in 100 people): diarrhea, nausea, vomiting.
Rare side effects (appear in less than 1 in 1,000 people): heart block (manifested by irregular pulse, dizziness, tiredness and fainting), dizziness (especially when standing up), thinning of hair, mood changes, confusion, memory loss, psychoses and/or hallucinations, tingling of the hands, vision disturbances, dry eyes, skin rash, easily appearing bruises (after decrease in platefets) or appearance of purple marks on the skin. In cases of worsening in patients with heart failure (manifested by shortness of breath and/or swelling of the ankles), in patients suffering from asthma or other respiratory problems, in patients suffering from blood circulation problems and worsening of symptoms in people suffering from psoriasis, contact the physician immediately!
Very rare side effects (appear in less than 1 in 10,000 people): severe muscle weakness (Myasthenia gravis), changes in blood cells or other blood components (your physician may request blood samples to check the effect of this medicine on your blood).
Side effects with unknown frequency: low blood sugar levels, the effect can appear in people with/without diabetes and it includes: newborns, infants, children, the elderly, hemodialysis patients, patients that have taken an overdose of Prolol® and people taking antidiabetics. This effect can also occur while fasting or in people with prolonged liver disease; seizures caused by low blood sugar levels.
Side effects that require special attention: slow heart beat (especially lower than 50 beats per minute), depression, difficulty breathing (rare), refer to your physician.
In cases of skin itching, ankles and feet swelling, hallucinations, cold hands and feet (rare), refer to your physician immediately!
If you experience side effects not mentioned in this leaflet, or if there is a change in your general health, consult your physician immediately.

Side effects and drug interactions in children and infants:

Parents should report to the attending physician about any side effects as well as any additional medicines given to the child!
See side effects and drug interactions listed above.

Dosage:

Dosage according to your physician's instructions only. Do not exceed the recommended dose.
This medicine should be taken at regular intervals as determined by the attending physician.
If you forget to take the medicine at the specified time, take the dose as soon as you remember, but skip the dose if less than 4 hours are left till the next dose.
Never take two doses together!
You must follow a strict low-sodium (salt) diet during treatment for high blood pressure.
Dosage for children: The physician will adjust the dosage according to the child's age or weight.

Directions for use: Can be crushed and can be halved. Swallow the medicine with a small amount of water, with food.

How can you contribute to the success of the treatment?

Complete your treatment as recommended by your physician. Even if there is an improvement in your health, do not discontinue the treatment with this medicine without consulting a physician. In any case, dosage reduction will be done gradually.

Avoid poisoning!

This medicine, and all other medicines, must be kept in a closed place out of the reach of children and/or infants to avoid poisoning.
If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.
Do not induce vomiting unless explicitly instructed to do so by a physician!
This medicine has been prescribed for the treatment of your illness, in another patient it may cause harm. Do not give this medicine to relatives, neighbors or acquaintances.
Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.

Storage: Store below 25°C.
It is recommended to keep the tablets in their original cardboard package.
Even if kept in their recommended package/storage conditions, medicines retain their potency for a limited period only. Please note the expiry date of this medicine! In any case of doubt, consult with the dispensing pharmacist.
Do not store different medicines in the same package.

Drug registration number:
Prolol® 10: 049802364500
Prolol® 40: 048372364600

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