## Patient package insert according to Pharmacists' Regulations (Preparations) – 1986

This medicine can be sold with a physician's prescription only

**PROLOL® 10, 40 mg, TABLETS**

Each tablet contains propranolol hydrochloride 10 or 40 mg respectively.
Inactive ingredients and allergens in the medicine – see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of the medicine".

**Read this entire leaflet carefully before using the medicine.** This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if you think that their medical condition is similar to yours.

## 1. What is the medicine intended for?

For the treatment of angina pectoris, high blood pressure, regulation of heart rhythm, tremors, preventive treatment after a myocardial infarction and preventive treatment for migraine.
**Therapeutic group**: non-selective blocker of the beta-type receptor, also known as "Beta-blocker".

## 2. Before using the medicine

**Do not use the medicine if:**

- You are hypersensitive (allergic) to the active substance (propranolol hydrochloride) or to any of the other ingredients this medicine contains (see section 6).
- You suffer or have suffered in the past from asthma or wheezing.
- You suffer from uncontrolled heart failure, or from other problems such as second or third degree heart block, a very slow or irregular heartbeat, very low blood pressure or severe blood flow disorders.
- You are fasting or have been fasting recently.
- You suffer from untreated pheochromocytoma (a tumour usually located near the kidneys and might cause high blood pressure), metabolic acidosis (high level of acid in the blood), Prinzmetal's angina (chest pain at rest).

**Special warnings regarding the use of the medicine**
**Before the treatment with Prolol, tell the doctor if:**

- You get allergic reactions (for example to insect bites).
- You suffer from diabetes, as the medicine may change your response to low blood sugar, which usually involves an increase in heart rate. Propanol may cause low blood sugar levels even in non-diabetic patients.
- You suffer from unstable angina (non exercise-induced sharp chest pain).
- You suffer from thyrotoxicosis. The medicine may mask symptoms of this condition.
- You suffer from kidney or liver problems (including cirrhosis of the liver). You may need to have certain tests during your treatment.
- You suffer from other medical conditions, such as blood circulation disorders, heart problems, breathlessness or swollen ankles.

**Drug interactions**
**If you are taking, have recently taken or might take other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.** Propranolol may affect the activity of certain medicines and other medicines can affect the activity of propranolol. In particular, inform the doctor or pharmacist if you are taking:

- Insulin or oral diabetes medications
- Verapamil, diltiazem, nifedipine, nisoldipine, nicardipine, isradipine, lacidipine (used to treat hypertension or angina)
- Hydralazine (to treat high blood pressure)
- Disopyramide, lidocaine, quinidine, amiodarone, propafenone (to treat irregular heartbeats)
- Digoxin (to treat heart failure)
- Adrenaline (heart activity stimulant)
- Ibuprofen or indomethacin (to treat pain and inflammation)
- Ergotamine, dihydroergotamine, rizatriptan (to treat migraines)
- Chlorpromazine or thioridazine (to treat psychiatric disorders)
- Cimetidine (to treat stomach problems)
- Rifampicin (to treat tuberculosis)
- Theophylline (to treat asthma)
- Warfarin (to thin the blood)
- Clonidine (to treat high blood pressure or migraine) - do not stop the treatment with clonidine unless instructed by the doctor. Discontinuation of clonidine treatment will be accompanied by precise instructions from the doctor.

**Use of the medicine and food**
The medicine should be swallowed with some water, with food.

**Use of the medicine and alcohol consumption**
Alcohol may affect the activity of the drug.

**Surgeries**
If you are about to undergo surgery, tell the anaesthesiologist or the medical staff that you are taking **Prolol**.

**Pregnancy and breastfeeding**
If you are pregnant or breastfeeding, may be pregnant, or are planning to become pregnant, consult a doctor or pharmacist before using the medicine.

**Driving and using machines**
It is likely that the drug will not affect the ability to drive or operate machinery. However, some people feel dizzy or tired when taking **Prolol**. If this happens to you, consult a doctor.
As for children - they should be warned about riding a bicycle or playing near the road, etc.

**Important information about some of the ingredients of the medicine**

- **Prolol** contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
- This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially "sodium-free".
- **Prolol 10** contains the food colour orange lake E-110, which may cause allergic reactions.

## 3. How to use the medicine?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.
The dosage and manner of treatment will be determined by the doctor only.
**Do not exceed the recommended dose.**

**Method of administration**
- The medicine should be swallowed with some water, with food.
- The tablet may be halved. There is no information regarding crushing or chewing.
- A low sodium (salt) diet must be observed during the treatment of hypertension.

**If you have accidentally taken a higher dosage**
If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

**If you forgot to take the medicine**
If you forgot to take this medicine at the designated time, take the dose as soon as you remember, unless it is almost time to take the next dose.
Do not take a double dose to make up for a forgotten dose.

Continue with the treatment as recommended by the doctor. Even if there is an improvement in your health, do not stop taking this medicine without consulting the doctor.

**If you stop taking the medicine**
Do not stop taking the medicine without consulting the doctor; in some cases, the treatment will be stopped gradually.

**Do not take medicines in the dark! Check the label and the dose each time you take a medicine.**
**Wear glasses if you need them.**
**If you have further questions on the use of this medicine, consult the doctor or pharmacist.**

## 4. Side effects

Like any medicine, the use of **Prolol** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

**Common side effects** (effects that occur in 1-10 out of 100 users):
- Cold fingers and toes
- Decreased heart rate
- Numbness and spasms in the fingers followed by a feeling of warmth and pain (Raynaud's disease)
- Sleep disorders, nightmares, fatigue

**Uncommon side effects** (effects that occur in 1-10 out of 1,000 users):
- Diarrhea, nausea, vomiting

**Rare side effects** (effects that occur in 1-10 out of 10,000 users):
- Worsening of breathing difficulties, if you suffer or have suffered in the past from asthma
- Shortness of breath and/or swollen ankles, if you suffer from heart failure
- Heart block, which can cause irregular heartbeat, dizziness, tiredness or fainting

- Dizziness, particularly when standing up
- Worsening of blood circulation, if you suffer from blood circulation problems
- Hair loss
- Mood changes, confusion, memory loss, psychoses and/or hallucinations (mental disorders)
- Tingling of the hands
- Vision disturbances, dry eyes
- Skin rash, including worsening of psoriasis, bruising more easily (following a decrease in blood platelets), the appearance of purple spots on the skin (purpura).

**Very rare side effects** (effects that occur in less than 1 in 10,000 users):
- Severe muscle weakness (myasthenia gravis)
- Changes to the blood cells or other components of the blood. The doctor may refer to blood tests to check if the medicine has any effect on the blood.

**Side effects with unknown frequency** (effects for which a frequency has not yet been determined):
- Low blood sugar levels may occur in diabetic and non diabetes patients, including newborns, infants and children, elderly patients, patients on haemodialysis or patients on medication for diabetes. Also in patients who are fasting or have been fasting recently or in patients with prolonged liver disease
- Seizure associated with low blood sugar levels
- Depression

**If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.**

Side effects can be reported to the Ministry of Health by clicking the link "דיווח על תופעות לוואי עקב טיפול תרופתי" found on the homepage of the Ministry of Health website (www.health.gov.il) directing to the online form for reporting side effects or via the link: https://sideeffects.health.gov.il

## 5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (תאריך תפוגה) stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store below 25°C.
- Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Additional information

**In addition to the active ingredient, the medicine also contains:**

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: blue lake E-132, red lake E-127

**What the medicine looks like and what the package contains:**

**Prolol 10:** peach coloured, round tablets, scored on one side.

**Prolol 40:** pink, round tablets, scored on one side.

Approved package sizes: 10, 28, 30, 48, 50, 56, 1000 tablets. Not all package sizes may be marketed.

Revised in September 2024 according to MOH guidelines

**Drug registration numbers at the national drug registry of the Ministry of Health:**
**Prolol 10:** 049802364500
**Prolol 40:** 048372364600

**Manufacturer and registration holder:**
Dexcel Ltd., 1 Dexcel St., Or Akiva 3060000, Israel