Package leaflet: Information for the patient

Probetol 10 mg Tablets
Probetol 40 mg Tablets

Propranolol hydrochloride

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 Probetol is and what it is used for
2. What you need to know before you take Probetol
3. How to take Probetol
4. Possible side effects
5. How to store Probetol
6. Contents of the pack and other information

1. What Probetol is and what it is used for

Probetol contains the active substance propranolol hydrochloride. Propranolol hydrochloride belongs to a group of medicines called beta-blockers. It has effects on the heart and circulation and also on other parts of the body and is used to treat the following conditions:
- High blood pressure (hypertension).
- Chest pain (angina).
- Some heart beat problems (arrhythmias).
- Protecting the heart after a heart attack.
- Preventing migraines.
- Essential tremor (shaking with an unknown cause).
- Anxiety.
- Some thyroid problems (such as thyrotoxicosis which is caused by an overactive thyroid gland).
- High blood pressure caused by a tumor, usually near the kidney (phaeochromocytoma).
- Prevention of bleeding in the oesophagus caused by high blood pressure in the liver.

2. What you need to know before you take Probetol

Do not take Probetol:
- If you or anyone in your family has ever had asthma or wheezing.
- If you are allergic to propranolol hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- If you have ever had any of the following heart problems:
  - heart failure which is not under control (this usually makes you breathless and causes your ankles to swell).
  - second- or third-degree heart block (a condition which may be treated by a pacemaker).
  - very slow or very uneven heart beats, very low blood pressure or very poor circulation.
  - a type of chest pain (angina) called Prinzmetal's angina.
- You have a tumour called phaeochromocytoma that is not being treated. This is usually near your kidney and can cause high blood pressure.
- You have been told that you have higher than normal levels of acid in your blood (metabolic acidosis).
- You have been fasting recently.

If any of the above applies to you, do not take Probetol and ask your doctor.

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine :
- If you get allergic reactions such things as insect stings. It is important to tell your doctor you are taking Probetol if you need treatment for an allergic reaction.
- Have any other health problems such as circulation disorders, heart problems, breathlessness or swollen ankles.
- Suffer from unstable angina (non exercise-induced sharp chest pain)
- If you have problems with your kidneys. You may need to have some check-ups during your treatment.
- If you have problems with your liver (such as cirrhosis of the liver). You may need to have some check-ups during your treatment.
- Have diabetes as Probetol may change your normal response to low blood sugar, which usually involves an increase in heart rate. Probetol may cause low blood sugar levels even in patients who are not diabetic.
- If you have thyrotoxicosis (a condition caused by an overactive thyroid gland). Your medicine may hide the symptoms of thyrotoxicosis.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Probetol.

Other medicines and Probetol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
In particular, tell your doctor if you are taking any of the following medicines:
- Verapamil
- Diltiazem
- Nifedipine
- Nisoldipine
- Nicardipine
- Isradipine
- Lacidipine, (which are used to treat hypertension or angina)
- Disopyramide
- Lidocaine
- Quinidine
- Amiodarone or propafenone (for irregular heartbeats)
- Digoxin (for heart failure)
- Adrenaline (a heart stimulant)
- Ibuprofen and indomethacin (for pain and inflammation)
- Ergotamine, dihydroergotamine or rizatriptan (for migraine)
- Chlorpromazine and thioridazine (for certain psychiatric disorders)
- Cimetdine (for stomach problems)
- Rifampicin (for the treatment of tuberculosis)
- Theophylline (for asthma)
- Warfarin (to thin the blood) and hydralazine (for hypertension).

If you are taking clonidine (for hypertension or migraine) and Probetol together, you must not stop taking clonidine unless your doctor tells you to do so. If it becomes necessary for you to stop taking clonidine, your doctor will give you careful instructions on how to do it.

Probetol with food and drink

The tablets should preferably be administered before meals.
If you frequently drink a lot of alcohol, tell your doctor before taking this medicine. This is because alcohol can affect how the medicine works.

Operations

If you go into hospital to have an operation, tell the anaesthetist that you are taking Probetol.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Driving and using machines

This medicine is unlikely to affect your ability to drive or use any tools or machines. However, some people may occasionally feel dizzy or tired when taking Probetol. If this happens to you, ask your doctor for advice.

Probetol contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Probetol

Always take this medicine exactly as your doctor has told you. Your doctor will tell you how many tablets to take each day and when to take them. Swallow your Probetol tablets with a drink of water.

Adults
- High blood pressure (hypertension): Initially 80 mg twice daily. The usual dose range is 160-320 mg daily.
- Chest pain (angina): Initially 40 mg two or three times daily. An adequate response is usually seen in the range 120-240 mg daily.
- Heart beat problems (arrhythmias): the usual dose is 10-40 mg three or four times daily.
- To protect the heart after a heart attack: the usual dose is 160 mg a day.
- Migraine and Essential tremor: Initially 40 mg two or three times daily.An adequate response is usually seen in the range 80-160 mg daily.
- Anxiety: the usual dose is 40 mg two or three times daily.
- Thyroid conditions (such as thyrotoxicosis): the usual dose is 10-40 mg three or four times daily
- Hypertrophic cardiomyopathy (thickened heart muscle): the usual dose range is 30 mg to 160 mg daily.
- Phaeochromocytoma: the usual dose is 30 mg to 60 mg a day.
- Bleeding in the oesophagus caused by high blood pressure in the liver: the usual dose range is 80 mg to 160 mg daily.

Use in children and adolescents

Under some conditions, Probetol can be used to treat children with these conditions. The dosage will be adjusted by the doctor according to the child's age or weight.

If you take more Probetol than you should

Propranolol is severely toxic if used in overdose. If you have accidently taken more than the prescribed dose or are experiencing symptoms of overdose, you should urgently seek medical attention.
If you accidentally take an overdose of your medicine, either call your doctor straight away, or go to your nearest hospital emergency department. Always take any remaining tablets, the container and the label with you, so that the medicine can be identified.

If you forget to take Probetol

If you forget to take a dose of this medicine, take it as soon as you remember and then take the next dose at its usual time. If it is almost time for your next dose you should simply take the next tablet at the usual time. Do not take a double dose (two tablets at once) to make up for a forgotten tablet.

If you stop taking Probetol

Do not stop taking Probetol without asking your doctor first. In some cases, you may need to stop taking this medicine gradually.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Probetol can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Common (may affect up to 1 in 10 people)
- Cold hands and feet
- The heart beating more slowly
- Numbness and spasm in your fingers which is followed by warmth and pain (Raynaud's disease)
- Disturbed sleep or nightmares
- Fatigue

Uncommon (may affect up to 1 in 100 people)
- Diarrhea
- Nausea
- Vomiting

Rare (may affect up to 1 in 1,000 people)
- Worsening of breathing difficulties, if you have or have had asthma
- Breathlessness and/or swollen ankles, if you also have heart failure
- Heart block which may cause an abnormal heart beat, dizziness, tiredness or fainting
- Dizziness(particularly on standing up)
- Worsening of your blood circulation, if you already suffer from poor circulation
- Hair loss
- Mood changes
- Confusion
- Memory loss
- Psychosis or hallucinations (disturbances of the mind)
- Tingling of your hands
- Disturbances of vision
- Dry eyes
- Skin rash, including worsening of psoriasis
- Bruising more easily (thrombocytopaenia)
- Purple spots on the skin (purpura)

Very rare (may affect up to 1 in 10,000 people)
- Severe muscle weakness (myasthenia gravis)
- There may be changes to some of the cells or other parts of your blood. It is possible that your doctor may occasionally take blood samples to check whether Probetol has had any effect on your blood.

Not known (frequency cannot be estimated from the available data)
- Low levels of sugar in the blood. This can happen in people with or without diabetes. This includes newborn babies, toddlers, children, elderly people, patients on artificial kidneys (haemodialysis) or patients on medication for diabetes. It may also occur in patients who are fasting or have been fasting recently or who have a long-term liver disease.
- Seizure linked to low levels of sugar in your blood.

Do not be alarmed by this list of possible events. You may not have any of them.
If you get any other undesirable events or if you think your medicine is causing any problems, tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist.This includes any possible side effects not listed in this leaflet.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Probetol
- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the blister and the outer packaging. The expiry date refers to the last day of that month.
- Do not store above 30ºC. Keep away from humidity.
- Do not use this medicine if you notice visible signs of deterioration.
- Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Probetol contains

The active substance is propranolol hydrochloride.
Each tablet of Probetol 10 mg contains 10 mg of propranolol hydrochloride.
Each tablet of Probetol 40 mg contains 40 mg of propranolol hydrochloride.
The other ingredients for Probetol 10 mg and 40 mg are: lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, colloidal anhydrous silica, magnesium stearate.

What Probetol looks like and contents of the pack

Probetol 10 mg are white round tablets.
Probetol 40 mg are white round tablets scored into two on one side.
Probetol 10 mg and 40 mg are available in boxes containing 50 tablets.

Marketing Authorisation Holder and Manufacturer

Pharmaline s.a.l. -Lebanon
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Contact us: pharmaline@maliagroup.com
Website: www.pharmaline.com.lb

Registration No for Probetol 10 mg tablets: 27591/94
Registration No for Probetol 40 mg tablets: 27592/94

This is a medicament:
- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists

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