

Propranolol 10 mg and 80 mg Tablets

Propranolol hydrochloride

RelonChem

PACKAGE LEAFLET: INFORMATION FOR THE USER

The product names propranolol 10 mg and 80 mg Tablets are collectively referred to as Propranolol Tablets in this leaflet.

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. What Propranolol Tablets are and what they are used for

Propranolol is one of a group of drugs called beta-blockers. Beta-blockers slow the heart and circulation and can affect other parts of the body e.g liver.

Propranolol can be used for many conditions including

- Hypertension (high blood pressure), angina (chest pains), some arrhythmias (disorders of heart rhythm), protection of the heart after a myocardial infarction (heart attack).
- Hypertrophic cardiomyopathy (thickening heart muscle).
- Prevention of migraine, essential tremor and anxiety.
- Thyrotoxicosis a thyroid condition caused by an overactive thyroid gland.
- Pheochromocytoma (high blood pressure due to a tumour usually near the kidney).
- Bleeding in the oesophagus caused by high blood pressure in the liver.

2. What you need to know before you take Propranolol Tablets

If you have ever had asthma or wheezing, do not take your Propranolol Tablets. Go back to your doctor or pharmacist.

Do not take Propranolol Tablets:

- If you are allergic to Propranolol or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Propranolol Tablets.

Propranolol Tablets should not be taken by people with heart failure which is not under control or people with certain other conditions such as heart block, very slow or very irregular heartbeats, very low blood pressure or very poor circulation. It should also not be taken by people who are fasting or have been fasting recently, people who have pheochromocytoma (high blood pressure due to a tumour usually near the kidney) which is not being treated or by people who have metabolic acidosis or a particular type of chest pain called Prinzmetal's angina. Your doctor will know about these conditions. If you have one of these conditions, make sure your doctor knows about it before you take Propranolol Tablets.

Talk to your doctor or pharmacist before taking Propranolol Tablets if you:

- Get allergic reactions to such things as insect stings.
- Have diabetes as Propranolol Tablets may change your normal response to low blood sugar, which usually involves an increase in heart rate. Propranolol Tablets may cause low blood sugar levels even in patients who are not diabetic.
- Suffer from unstable angina (non exercise-induced sharp chest pain).

- Have thyrotoxicosis. Propranolol Tablets may hide the symptoms of thyrotoxicosis.
- Have kidney or liver problems (including cirrhosis of the liver). If so, talk to your doctor because you may need to have some check-ups during your treatment.
- Have any other health problems such as circulation disorders, heart problems, breathlessness or swollen ankles.

Other medicines and Propranolol Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Propranolol Tablets can interfere with the action of some other drugs and some drugs can have an effect on your medicine. The drugs which can cause some problems when taken together with your medicine are:

- 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 indometacin (for pain and inflammation)
- Ergotamine, dihydroergotamine or rizatriptan (for migraine)
- Chlorpromazine and thioridazine (for certain psychiatric disorders)
- Cimetidine (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 propranolol tablets 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.

Propranolol Tablets with food, drink and alcohol

Propranolol Tablets should be swallowed with a drink of water.

If you frequently drink a lot of alcohol, this may reduce the effect of your medicine.

Operations

If you go into hospital to have an operation, tell the anaesthetist or the medical staff that you are taking Propranolol Tablets.

Pregnancy, breast-feeding and fertility

Before taking these tablets tell your doctor if you are, you think you might be or are planning to become pregnant. You should not use Propranolol Tablets if you are breast-feeding or are planning to breast-feed your baby.

Driving and using machines

Propranolol Tablets may make you feel dizzy or tired. If affected do not drive or operate machinery.

Propranolol Tablets contain 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 Propranolol Tablets

Always take Propranolol Tablets exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

Propranolol tablets should be swallowed with a drink of water.

Your doctor will have decided how many Propranolol tablets you need to take each day depending on your condition. Follow your doctor's instructions about when and how to take your tablets. Please read the label on the container.

This will also tell you how many tablets to take and when you should take them. Ask your doctor or pharmacist if you are not sure.

The following table shows the usual total daily oral dosage for an adult:

Condition	Dose
Hypertension (high blood pressure)	160 to 320 mg
Angina (chest pain)	120 to 240 mg
Arrhythmias* (disorders of the heart rhythm)	30 to 160 mg
Protection of the heart after a heart attack	160 mg
Prevention of migraine* and essential tremor	80 to 160 mg
Anxiety	40 to 120 mg
Certain thyroid conditions* (such as thyrotoxicosis)	30 to 160 mg
Hypertrophic cardiomyopathy (thickening heart muscle)	30 to 160 mg
Phaeochromocytoma*	30 to 60 mg
Bleeding of the oesophagus caused by high blood pressure in the liver	80 to 160 mg

*Under some circumstances, propranolol tablets 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. Older people may start on a lower dose.

If you take more Propranolol Tablets than you should:

If you swallow too many tablets or someone else accidentally takes your medicine, contact your doctor, pharmacist or nearest hospital straight away. Always take any remaining tablets, the container and the label with you, so that the medicine can be identified.

Propranolol is severely toxic if used in a overdose. If you have accidentally taken more than the prescribed dose or are experiencing symptoms of an overdose, you should urgently seek medical attention.

If you forget to take Propranolol Tablets

If you forget to take your medicine, take your dose when you remember and then take your next dose at the usual time.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Propranolol Tablets

Do not stop taking Propranolol Tablets without first discussing it with your doctor. In some cases it may be necessary to stop taking the medicine gradually.

If you have any further questions on the use of Propranolol Tablets ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines this medicine can cause side effects, although not everybody gets them.

Common: may affect up to 1 in 10 people

- Cold fingers and toes
- The heart beating more slowly
- Numbness and spasm in the fingers which is followed by warmth and pain (Raynaud's phenomenon)
- Disturbed sleep/nightmares
- Fatigue.

Uncommon: may affect up to 1 in 100 people

- Diarrhoea
- 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 the 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 Propranolol Tablets has had any effect on your blood.

Not known: frequency cannot be estimated from the available data

- Low levels of blood sugar may occur in diabetic and non-diabetic patients including the new-born, toddlers and children, elderly patients, 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 the blood.
- Depression.

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the yellow card scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Propranolol Tablets

Keep this medicine out of the sight and reach of children.

Do not use Propranolol Tablets after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not store the tablets above 25°C. Store in the original container.

Do not throw away any medicines via wastewater or household waste. 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

The Propranolol Tablets contain

The active substance is Propranolol hydrochloride.

The other ingredients are lactose, talc, stearic acid, magnesium stearate, hypromellose, polyethylene glycol, titanium dioxide (E171) and carmine (E120). In addition to these ingredients the 80 mg tablets also contain microcrystalline cellulose.

What Propranolol Tablets look like and contents of the pack

The 10 mg tablets are pink, film-coated biconvex tablets embossed '10' on one face. The 80 mg tablets are pink, film-coated biconvex tablets with a breakline on one face and embossed '80' on the other.

Propranolol 10 mg Tablets are available in pots of 20, 50, 500 and 1,000 tablets and blister packs of 28 tablets.

Propranolol 80 mg Tablets are available in pots of 20, 50 and 500 tablets and blister packs of 56 tablets.

Marketing Authorisation Holder and Manufacturer

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