

Package leaflet: Information for the user

Propranolol 10 mg Tablets
Propranolol 40 mg Tablets
Propranolol 80 mg Tablets
Propranolol 160 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. See section 4.

What is in this leaflet:

1. What Propranolol Tablets are and what they are used for
2. What you need to know before you take Propranolol Tablets
3. How to take Propranolol Tablets
4. Possible side effects
5. How to store Propranolol Tablets
6. Contents of the pack and other information

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

Propranolol belongs to a group of medicines called beta blockers. It is used to:

- treat pain in the chest (due to poor blood flow to the heart muscle)
- treat high blood pressure (hypertension)
- help prevent additional heart attacks
- treat tremors (shaking with an unknown cause)
- control irregular or fast heart beats
- control fast heart rate and other symptoms caused by an over active thyroid gland (thyrotoxicosis)
- treat high blood pressure caused by a tumour near a kidney (phaeochromocytoma)
- reduce severe headaches (migraine)
- prevent stomach bleeding in patients with high blood pressure in their liver or swollen blood vessels in their gullet
- Under some conditions, propranolol can be used to treat children with

arrhythmias (disorders of the heart rhythm). The dosage will be adjusted by the doctor according to the child’s age or weight

It works by the effects it has on the heart and circulation and also on other parts of the body.

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

Do not take Propranolol if you:

- are allergic to Propranolol hydrochloride or any of the other ingredients of this medicine (see section 6)
- have untreated/uncontrolled heart failure
- are in shock caused by heart problems
- have severe heart defects (second or third degree heart blocks) which may be treated by a pacemaker
- suffer with heart conduction or rhythm problems
- have a very slow or very uneven heart rate
- have increased acidity of the blood (metabolic acidosis)
- are on a strict fasting diet
- suffer from asthma, wheezing or any other breathing difficulties
- suffer from untreated phaeochromocytoma (high blood pressure due to a tumour near the kidney)
- suffer from severe blood circulation problems (which may cause your fingers and toes to tingle or turn pale or blue)
- suffer from a tight, painful feeling in the chest in periods of rest (Prinzmetal’s angina)
- have very low blood pressure

If you think that one of these situations applies to you, or if you are in any doubt, talk to your doctor before you start using Propranolol.

Warnings and precautions

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

- have a history of allergic reactions, for example to insect stings
- have poor blood circulation or controlled heart failure
- have sharp chest pain which is not caused by exercise (unstable angina)
- suffer from muscle weakness (myasthenia gravis)
- have a weak heart or first degree heart block
- have kidney disease or problems with your kidneys. You may need to have check ups during your treatment
- have liver disease or problems with your liver (such as cirrhosis of the liver).

You may need to have some check-ups during your treatment

- this medicine may mask symptoms of hyperthyroidism (increased appetite, weight loss, sweating)

- have diabetes. Your medicine may lower blood sugar levels (hypoglycaemia) leading to slow heart rate.
- have a condition caused by an overactive thyroid gland (thyrotoxicosis). Your medicine may hide the symptoms of thyrotoxicosis.
- suffer from Raynaud’s disease (cold sensations in fingers and toes) or intermittent claudication (narrowing of arteries in the legs causing pain on walking)
- Have conditions like chronic obstructive pulmonary disease and bronchospasm because the use of Propranolol can aggravate these conditions.
- Use channel blockers with negative inotropic effects like verapamil and diltiazem (please refer to ‘Other medicines and Propranolol’).

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

Other medicines and Propranolol Tablets

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. These medicines include the following:

- barbiturates (to treat severe insomnia)
- MAO inhibitors (to treat depression)
- disopyramide, flecanide, lidocaine, quinidine amiodarone, propafenone (used to treat life-threatening heart conduction or rhythm problems)
- fingolimod (to treat multiple sclerosis)
- verapamil, bepridil, nifedipine, nisoldipine, nicardipine, isradipine, lacidipine and diltiazem (to treat heart diseases such as high blood pressure or chest pain)
- indometacin or ibuprofen (to treat pain and inflammation)
- cimetidine (to treat stomach ulcers)
- adrenaline (epinephrine, used in anaphylactic shock) a medicine that stimulates the heart
- fluvoxamine (used to treat depression)
- clonidine, moxonidine and methyl dopa (used to treat high blood pressure). If you are taking clonidine and Propranolol together, do not stop taking clonidine unless your doctor tells you to do so. If you have to stop taking clonidine, your doctor will give you careful instructions about how to do it.
- digoxin (for heart problems)
- warfarin (to thin the blood) and hydralazine (for hypertension)
- chlorpromazine or thioridazine (for mental illness)
- medicines to treat diabetes including insulin
- medicines to treat migraine, like rizatriptan, ergotamine or dihydroergotamine

- rifampicin (to treat infection/tuberculosis)
- Fingolimod (for treating multiple sclerosis)
- theophylline (treating asthma and reversible airways obstruction)
- smoking tobacco

If you are taking clonidine (for hypertension or migraine) and Propranolol 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.

Pregnancy, breast-feeding and fertility

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

Propranolol is not recommended during pregnancy or breastfeeding.

Driving and using machines

Because of the side effects, i.e. tiredness and dizziness, it is conceivable that the ability to drive and use machines might be affected.

Propranolol Tablets contain Lactose

If you have been told that you have an intolerance to some sugars, contact your doctor before taking this medicine, as it contains lactose.

Propranolol Tablets with food, drink and alcohol

If you frequently drink a lot of alcohol, talk to your doctor before having this medicine. This is because alcohol can affect how the medicine works.

Anaesthetics or tests

If you are going to have an anaesthetic or any blood or urine tests, please tell your doctor or dentist that you are taking Propranolol tablets. If you see another doctor or go into hospital, let them know what medicines you are taking. This is because you can get low blood pressure (hypotension) if you are given certain anaesthetics while you are taking propranolol.

3. How to take Propranolol Tablets

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Swallow your propranolol tablets with a drink of water before meals. Swallow whole. Do not chew. The score line is not intended for breaking the tablet. Do not stop taking this medicine unless your doctor tells you to stop.

The recommended dose is:

Adults:

- Chest pain (Angina): initially 40 mg two or three times a day, maximum recommended dose 120-240 mg a day.

- High Blood pressure (Hypertension): initially 40 mg two or three times daily, which may be increased by 80 mg per day, up to 160-320 mg a day is recommended.
- Heart attack (post myocardial infarction) - initially 40 mg two to three times daily, later dose may be increased to 80 mg twice daily.
- Tremor - 40 mg two to three times daily.
- Irregular heart rhythms - 10 mg to 40 mg two or three times a day.
- Over active thyroid gland - your dose may be decided based on clinical response.
- Phaeochromocytoma
 - Before an operation-60 mg a day for 3 days
 - Non operable treatment dose- 30 mg a day
- Migraine - initially 40 mg two or three times a day, upto 80-160 mg a day.
- Liver disease due to high blood pressure - initially 40 mg twice a day, maximum recommended dose 160 mg twice a day

Paediatric population:
Arrhythmias: Under some conditions, propranolol can be used to treat children with arrhythmias (disorders of heart rhythm). The dosage will be adjusted by the doctor according to the child’s age or weight.

Elderly: Your dose may be decided based on clinical response

Liver or kidney failure:
Your dose may be decided based on clinical response.

If you forget to take Propranolol Tablets

If you forget to take a dose, take it as soon as you remember. However, if it is almost time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

If you take more Propranolol Tablets than you should

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

Overdose causes an excessively slow heart rate, too low blood pressure, heart failure and breathing difficulty with symptoms such as fatigue, hallucinations, fine tremor, confusion, nausea, vomiting, body spasms, fainting or coma, low blood sugar.

If you stop taking Propranolol Tablets

If you stop taking the Propranolol Tablets suddenly you may experience unpleasant side effects including sweating, shaking, worsening of angina, irregular heart beat, heart attack or death.

Withdrawal should be gradual.

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

4. Possible side effects

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

Stop treatment and contact a doctor at once if you have the following symptoms:

- **intolerance to Propranolol** such as slow heart rate and low blood pressure causing dizziness, light headedness, fainting or blurred vision.
- **allergic reaction** such as itching, difficulty breathing or swelling of the face, lips, throat or tongue.

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

Common (may affect up to 1 in 10 people)

- tiredness, cold extremities, difficulty in sleeping (these symptoms usually disappear)
- slow or irregular heartbeat, severely restricted blood flow to the fingers and toes (Raynaud’s syndrome)
- nightmares or disturbed sleep, shortness of breath
- Fatigue

Uncommon (may affect up to 1 in 100 people)

- feeling sick (nausea) or being sick (vomiting), diarrhoea (these symptoms usually disappear)

Rare (may affect up to 1 in 1000 people)

- your medicine may alter the number and types of your blood cells such as reduce the number of platelets in your blood which may make you bruise more easily. If you notice increased bruising, nosebleeds, sore throats or infections, you should tell your doctor who may want to give you a blood test
- worsening of heart failure or heart block (which may cause an abnormal heart beat, dizziness, tiredness or fainting on standing/ low blood pressure
- skin rash, red and crusty patches of skin covered with silvery scales (worsening of psoriasis), hair loss or thinning of hair, dry flaky skin
- seeing, hearing or feeling things that seem real, but do not happen (hallucinations), mood changes, pins and needles, severe mental disorder (psychoses), feeling confused, memory loss
- dry eyes, visual disturbances
- bronchospasm/difficulty breathing in patients with asthma or history of breathing problems
- being unable to think with clarity
- abnormal skin sensations (as tingling or tickling or burning)

- swelling of the blood vessels below the skin, which may be painful and accompanied by redness
- swelling of the skin which may occur in the face, tongue, larynx, abdomen, or arms and legs (angioedema)
- Purple spots on the skin (purpura)
- Narrowing of arteries in the legs causing pain on walking (Exacerbation of intermittent claudication)

Very rare (may affect up to 1 in 10,000 people)

- severe muscle weakness (myasthenia gravis)
- Low levels of sugar in the blood (hypoglycaemia). This can happen in people with or without diabetes. This includes elderly people, people on artificial kidneys (haemodialysis) or people taking medicines for diabetes. It may also happen if you are fasting or in people with a long-term liver disease.
- excessive sweating

Not known (frequency cannot be estimated from the available data)

- Headache or seizure linked to low levels of sugar in the blood.
- Inability in a man to achieve an erection (impotence)
- Decrease in renal blood flow
- Joint pain(arthralgia)
- Constipation
- Dry mouth
- Shortness of breath or breathlessness (dyspnoea)
- Conjunctivitis (inflammation of the eye also called ‘pink eye’)
- Depression
- Severe and dangerous lowered white blood cell count (agranulocytosis)
- Worsening of angina pectoris (chest pains)
- Over active thyroid gland (Masking signs of thyrotoxicosis)

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. 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 this medicine after the expiry date which is stated on the label (EXP.). The expiry date refers to the last day of that month.
- This medicinal product does not require any special storage conditions.

- 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 to protect the environment.

6. Contents of the pack and other information

What Propranolol Tablet contains

- The active substance is Propranolol Hydrochloride. Each tablet contains either 10mg, 40mg, 80mg or 160mg of the active substance.
- The other ingredients are Lactose, Maize Starch, Povidone, Sodium Starch Glycolate, Magnesium Stearate, Hydroxypropyl Methyl Cellulose, Polyethylene Glycol 400, Titanium Dioxide (E171) and Opaspray M-1-1300B pink.

What Propranolol Tablets look like and contents of pack:

- **Propranolol 10 mg Tablets** are pink biconvex film coated tablets embossed with ‘1’ on one side and break line on the other side
- **Propranolol 40 mg Tablets** are pink biconvex film coated tablets embossed with ‘2’ on one side and break line on the other side
- **Propranolol 80 mg Tablets** are pink biconvex film coated tablets embossed with ‘3’ on one side and break line on the other side
- **Propranolol 160 mg Tablets** are pink biconvex film coated tablets embossed with ‘4’ on one side and break line on the other side
- Propranolol Tablets are available in packs of 28 and 56 tablets for all strengths. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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To request a copy of this leaflet in braille, large print or audio format, please contact the marketing authorisation holder at the address (or telephone, fax, email) above.