

PACKAGE LEAFLET: INFORMATION FOR THE USER

Propranolol 10 mg film-coated tablets
Propranolol 40 mg film-coated tablets
Propranolol 80 mg film-coated 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 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 of the side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Propranolol is and what it is used for

Propranolol belongs to the group of 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 overactive thyroid gland (thyrotoxicosis)
- treat high blood pressure caused by a tumour near a kidney (pheochromocytoma)
- reduce severe headaches (migraine)
- prevent stomach bleeding in patients with high blood pressure in their liver or swollen blood vessels in their gut.
- 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

Do not take Propranolol:

- if you are allergic (hypersensitive) to propranolol hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- have untreated/uncontrolled heart failure
- shock caused by heart problems

- severe heart defects (second or third degree heart blocks) a condition which may be treated by a pacemaker
- suffer with heart conduction or rhythm problems
- have a very slow or very uneven heart rate
- 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 pheochromocytoma (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 or nurse before taking Propranolol if you:

- have a history of allergic reactions, for example to insect stings
- have poor blood circulation or controlled heart failure
- 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)

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

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines This includes medicines that you buy without a prescription and herbal medicines. This is because Propranolol can affect the way some other medicines work and some medicines can have an effect on Propranolol.

In particular, tell your doctor if you are taking any of the following medicines:

- barbiturates (to treat severe insomnia).
- MAO inhibitors (to treat depression).
- Propafenone, disopyramide, lidocaine, quinidine or amiodarone (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)
- disopyramide, quinidine and amiodarone, lidocaine or flecanide (to treat irregular heartbeat and arrhythmias)

- 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 methyldopa (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)
- chlorpromazine or thioridazine (for mental illness)
- medicines to treat diabetes including insulin
- medicines to treat migraine, like rizatriptan, ergotamin or dihydroergotamine
- rifampicin (to treat infection/tuberculosis)
- theophylline (treating asthma and reversible airways obstruction)
- smoking tobacco

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.

Taking Propranolol with food and drink

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.

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.

Important information about some of the ingredients of Propranolol:

Propranolol 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 Propranolol

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

Swallow your propranolol tablets with a drink of water before meals. Swallow whole. Do not chew.

Do not stop taking this medicine unless your doctor tells you to stop.

Adults :

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

- High blood pressure (hypertension) - initially 40mg two or three times daily, which may be increased by 80mg per day, upto 160-320mg 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.
- Pheochromocytoma
 - before an operation - 60mg a day for 3 days.
 - non operable treatment dose - 30mg a day.
- Migraine: initially 40mg two or three times a day, upto 80-160mg a day.
- Liver disease due to high blood pressure - initially 40mg twice a day, maximum recommended dose 160 mg twice a day

Pediatric 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 take more Propranolol than you should

If you have accidentally taken more than the prescribed dose, contact your nearest casualty department or tell your doctor or pharmacist at once. 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 forget to take Propranolol

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 stop taking Propranolol

If you stop taking 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, pharmacist or nurse.

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

Uncommon may affect up to 1 in 100 people):

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

Rare (may affect up to 1 in 1,000 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/fainting on standing, dizziness
- skin rash, 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
- Being unable to think with clarity
- abnormal skin sensations (as tingling or tickling or itching or burning)
- swelling of the blood vessels below the skin, which may be painful and accompanied by redness.

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.
- sweating

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

- a pain in the head.
- an acute blood disorder
- difficulty in breathing
- signs of hyperthyroidism may be hidden
- changes in blood fats, changes in kidney functions
- changes in blood sugar levels
- fits (seizures) linked to low blood sugar levels
- worsening of chest pain, depression
- constipation, dry mouth, eye infections
- changes in sex drive or potency
- joint pain

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. By reporting side effects you can help provide more information on the safety of this medicine.

For UK - You can also report side effects directly via the Yellow Card Scheme at:
www.mhra.gov.uk/yellowcard

For Malta- ADR Reporting
The Medicines Authority
Post-Licensing Directorate
203 Level 3, Rue D'Argens
GŻR-1368 Gżira
Website: www.medicinesauthority.gov.mt
e-mail:
postlicensing.medicinesauthority@gov.mt

5 How to store Propranolol

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

- This medicinal product does not require any special storage conditions.
- Do not use this medicine after the expiry date stated on the label after 'EXP'. The expiry date refers to the last day of that month.
- 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 contains

The active ingredient is propranolol hydrochloride. Each film-coated tablet contains 10 mg, 40 mg or 80 mg propranolol hydrochloride.

The other ingredients are:

maize starch
lactose monohydrate
cellulose microcrystalline (E460)
magnesium stearate

Composition of the tablet coating,
hypromellose (E464)
cellulose microcrystalline (E460)
acetylated monoglycerides and diglycerides
titanium dioxide (E171)

What Propranolol looks like and contents of the pack

10 mg: White to off-white, round, biconvex (rounded on both sides) film-coated tablets with the inscription 'AI' on one side and a scoreline on the other side.

40 mg: White to off-white, round, biconvex (rounded on both sides) film-coated tablets with the inscription 'AL' on one side and a scoreline on the other side.

80 mg: White to off-white, round, biconvex (rounded on both sides) film-coated tablets with the inscription 'AM' on one side and a scoreline on the other side.

The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

PVC-PVdC/ ALU Blister in Pack sizes of 25, 28, 30, 50, 56, 60, 100 and 250 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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