

PROPRANOLOL 10 mg, 40 mg, 80 mg AND 160 mg TABLETS

PACKAGE LEAFLET: INFORMATION FOR THE USER

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.

IN THIS LEAFLET:

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1 What propranolol is and what it is used for

- Propranolol is a type of drug called a beta-blocker
- Propranolol is used for:
 - high blood pressure
 - angina pectoris (chest pain)
 - long term prevention of further heart attacks, if you have already had one
 - heart rhythm problems or a racing heartbeat
 - anxiety
 - migraine (as a preventative treatment)
 - involuntary muscle movements
 - an over-active thyroid gland.

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
- have a history of wheezing or asthma
- suffer from poor circulation
- suffer from Prinzmetal's angina (angina due to coronary artery spasm)
- have a slow heart rate
- suffer from other heart problems such as heart failure, cardiogenic shock, heart block or sick sinus syndrome
- suffer from uncontrolled heart failure
- have low blood pressure
- have an adrenal tumour (phaeochromocytoma) resulting in high blood pressure, flushing, and diarrhoea
- suffer from metabolic acidosis (an imbalance of the body's acid-base balance)
- undertake or have recently undertaken prolonged periods of fasting.

Warnings and precautions

Talk to your doctor before taking this medicine if you:

- suffer from liver or kidney problems
- are undergoing treatment for diabetes
- have thyroid problems.

If you are to have surgery, propranolol should be withdrawn 24 hours before as it may interfere with response to stress.

Propranolol may increase reactions to a number of allergens.

Other medicines and propranolol Tell your doctor if you are taking any of the following:

- sympathomimetic drugs such as adrenaline
- ergotamine (for migraine)
- prostaglandin synthetase inhibitors used to treat inflammatory conditions
- other drugs for other heart conditions such as flecainide, diltiazem, nifedipine or digoxin
- cimetidine, hydralazine or chlorpromazine
- quinidine, propafenone, rifampicin, theophylline, warfarin, thioridazine or dihydropyridine
- calcium channel blockers e.g. nifedipine, nisoldipine, nifedipine, isradipine or lacidipine
- drugs used to treat diabetes including insulin.

You should warn your doctor or dentist that you are using Propranolol if you are going to receive an anaesthetic. Some anaesthetics (e.g. ether, trichloroethylene) should not be used with Propranolol. Propranolol may also increase the effects of lidocaine.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Propranolol with food and drink

- DO NOT drink alcohol whilst taking these tablets, as it may interfere with the action of Propranolol.

Pregnancy and breast-feeding

- Propranolol is not recommended if you are pregnant, planning to become pregnant or are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

- Propranolol may cause drowsiness and dizziness. If affected, DO NOT drive or operate machinery.

Propranolol contains:

Lactose

Patients who are intolerant to lactose should note that Propranolol tablets contain a small amount of lactose.

If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine

Sodium

This medicine contains less than 1 mmol sodium (23 mg) per Tablet, that is to say essentially 'sodium-free'

3 How to take propranolol

Always take Propranolol exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The tablets should be swallowed preferably with a glass of water. Propranolol can be taken with or without food. The usual dose is:

Adults including the Elderly

- **High Blood Pressure:** 80 mg twice daily. This may subsequently be increased by your doctor to a maintenance dose of between 160 - 320 mg daily.
- **Angina Pectoris:** 40 mg two or three times daily. This may then be adjusted by your doctor to a usual maintenance dose of between 120 - 240 mg per day.
- **Long term prevention of further Heart Attack:** Treatment should begin 5 - 21 days after the initial heart attack with 40 mg taken four times daily for two or three days. The dose should then be increased to 80 mg taken twice daily. In some cases, your doctor may adjust this dose according to your response to treatment.
- **Heart Rhythm Problems: Overactive Thyroid Gland:** The dose for adults is 10 - 40 mg three or four times daily.
- **Anxiety:**
 - 40 mg daily, for immediate relief of acute situational anxiety (fear triggered by a specific situation such as being in or on public transportation, tunnels, bridges, lifts, planes, cars, or enclosed spaces)
 - 40 mg two or three times per day, for longer term treatment of generalised anxiety disorder (also known as GAD, a condition characterised by persistent and excessive anxiety and worry that lasts for at least six months). Your doctor will review your dosage after 6 to 12 months.
- **Prevention of Migraine:** The dose for adults is 40 mg two or three times daily. This may then be increased by your doctor to between 80 - 160 mg per day.
- **Involuntary Muscle Movements:** 40 mg two or three times daily. This may then be increased by your doctor to between 80 - 160 mg per day.

Use in Children

- **Heart Rhythm Problems; Overactive Thyroid Gland**

Your doctor will calculate the appropriate dose for your child based on the child's body weight. The dose should be taken three or four times daily.

• **Prevention of migraine**

For children under 12 years old, 20 mg two or three times daily.

Older children may be given the adult dose.

Patients with kidney problems

A reduced starting dose may be given.

If you take more Propranolol than you should

If you (or someone else) swallow a lot of the tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. An overdose is likely to cause low blood pressure, breathlessness, confusion, low blood sugar levels, slow pulse rate and heartbeat, unconsciousness. Please take this leaflet, any remaining tablets and the container with you to the hospital or doctor so that they know which tablets were consumed.

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.

If you forget to take Propranolol

If you forget to take a tablet, take one as soon as you remember, unless it is time to take the next one. DO NOT take a double dose to make up for a forgotten tablet dose.

If you stop taking Propranolol

DO NOT stop taking your medicine without talking to your doctor first, even if you feel better.

Your treatment with Propranolol must not be stopped suddenly. If it is necessary to stop treatment, your doctor should reduce your dose gradually.

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

4 Possible side effects

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

Stop taking the tablets and tell your doctor immediately or go to the casualty department at your nearest hospital if the following happens:

- an allergic reaction causing swelling of the lips, face or neck leading to severe difficulty in breathing or severe skin rash or hives.

This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

Tell your doctor if you experience any of the following side effects:

- heart problems such as a very slow heart rate, heart failure getting worse (symptoms may include feeling breathless or swollen ankles) or heart block (symptoms may include slow or irregular heartbeat, shortness of breath, dizziness and fainting, pain or discomfort in your chest)
- low blood pressure, which may make you feel dizzy or light headed on standing
- breathlessness or wheezing (sometimes with a fatal outcome in patients with a history of asthma or hay fever)
- blood disorders (symptoms may include paleness of skin, fever, unusual bleeding or unexplained bruising)
- pain in the calf muscles, muscle weakness
- low levels of sugar in the blood (hypoglycaemia) may occur in children (frequency is unknown). Symptoms may include weakness, headache, feeling hungry, double vision, and mood changes, aggressive or abnormal behaviour).
- seizure linked to low levels of sugar in the blood (frequency is unknown)
- being unable to distinguish between reality and your imagination, hallucinations (hearing, or seeing, things that are not there), or delusions (believing things that are untrue)
- skin troubles such as rashes or itching
- dry eyes.

Not all of these effects are serious, but your doctor may decide to stop your treatment with Propranolol.

The following side effects have also been reported. Tell your doctor if you get any of these and they are troubling you:

- visual disturbances
- confusion, mood changes
- pins-and-needles

- nightmares
- poor circulation, which makes the fingers and toes pale, cold and numb
- worsening of existing psoriasis (patches of thickened and sore skin)
- hair loss.

The following are minor side effects. If you get these, and they last for longer than a few days, tell your doctor:

- feeling or being sick, diarrhoea
- tiredness, and/or difficulty in sleeping.

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

Keep out of the sight and reach of children.

Store in a dry place. Protect from light. Do not store above 25°C.

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

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Contents of the pack and other information

What Propranolol tablets contain:

- The active ingredient is 10, 40, 80 or 160 mg of propranolol hydrochloride
- The other ingredients are maize starch, lactose monohydrate, Starch pregelatinised, sodium starch glycolate, Silica Colloidal Anhydrous and magnesium stearate (E572)
- The coating contains hypromellose (E464), macrogol, erythrosine (E127), brilliant blue (E133), titanium dioxide (E171) and iron oxide (E172)
- The tablets are polished with carnauba wax.

What Propranolol tablets look like and contents of the pack:

- Propranolol tablets are dark pink, biconvex, film coated tablets, engraved on one side with a breakline on the reverse. The engraving marks for each tablet strength are:
10 mg: Berk 1Z1 or 1Z1
40 mg: Berk 2Z1 or 2Z1
80 mg: Berk 3Z1 or 3Z1
160 mg: Berk 4Z1 or 4Z1.
- All strengths are available in pack sizes of 7, 10, 14, 21, 28, 30, 56, 60, 84, 90, 100, 110, 112, 120, 150, 160 and 168 tablets
- Other pack sizes are available for each strength as follows:
10 mg: 50, 500, 1,000 and 40,000 tablets
40 mg: 50, 500, 1,000 and 20,000 tablets
80 mg: 500 and 1,000 tablets
160 mg: 8000 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation holder:
Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

Manufacturer:

Teva Pharmaceutical Works Co. Ltd Pallagi Street 13, Debrecen, H-4042, Hungary

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