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Package leaflet: Information for the user

Propranolol 10mg film-coated tablets  
Propranolol 40mg 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.
- 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 your 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 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 contains propranolol hydrochloride which 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. Propranolol can be used for many conditions including:

- Hypertension (high blood pressure)
- Angina (chest pain)
- Some arrhythmias (disorders of heart rhythm)
- Protection of the heart after a myocardial infarction (heart attack)
- Migraine
- Essential tremor, anxiety
- Certain thyroid conditions (such as thyrotoxicosis, which is caused by an overactive thyroid gland)
- Hypertrophic cardiomyopathy (thickened heart muscle)
- 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

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 if you:

- are allergic (hypersensitive) to propranolol hydrochloride 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.

Propranolol should also 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.

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

- Get allergic reactions to such things as insect stings.
- Have diabetes as Propranolol may change your normal response to low blood sugar, which usually involves an increase in heart rate. Propranolol 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 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

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Propranolol 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 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 with food, drink and alcohol

Alcohol may affect how this medicine works.

Operations

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

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.

Driving and using machines

Your medicine is unlikely to affect your ability to drive or to operate machinery. However, some people may occasionally feel dizzy or tired when taking Propranolol. If this happens to you, ask your doctor for advice.

This medicine contains lactose monohydrate

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

This medicine contains 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 this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Propranolol film-coated tablets should be swallowed with a drink of water. Your doctor will have decided how many 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 recommended total daily dosages for an adult:

Hypertension (high blood pressure)	160 mg to 320 mg
Angina (chest pains)	120 mg to 240 mg
Arrhythmias (disorders of heart rhythm)*	30 mg to 160 mg
Protection of the heart after a heart attack	160 mg

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Prevention of migraine*	80 mg to 160 mg
Essential tremor	80 mg to 160 mg
Anxiety	40 mg to 120 mg
Certain thyroid conditions (such as thyrotoxicosis)*	30 mg to 160 mg
Hypertrophic cardiomyopathy (thickened heart muscle)	30 mg to 160 mg
Phaeochromocytoma*	30 mg to 60 mg

Bleeding in the oesophagus caused by high blood pressure in the liver 80 mg to 160 mg

\*Under some circumstances, propranolol 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.

Elderly people may be started on a lower dose.

#### If you take more Propranolol 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.

If you accidentally take an overdose of your medicine, either call your doctor straight away, or go to your nearest hospital casualty 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 Propranolol

If you forget to take a dose, take it as soon as you remember and then take your next dose at the usual time. Don't take two doses at the same time. If you are worried, ask your doctor or pharmacist for advice.

#### If you stop taking Propranolol

Do not stop taking your medicine without talking to your doctor first. In some cases, it may be necessary to stop taking the 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, this medicine 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 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, sometimes with fatal outcome, 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 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 newborn, 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 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](http://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 this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after 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 contains

- The active substance is propranolol hydrochloride. Each film-coated tablet contains 10 mg and 40 mg propranolol hydrochloride.
- The other ingredients are  
*Tablet core:* Cellulose, Microcrystalline (Grade101), Lactose Monohydrate, Maize Starch, Sodium Starch Glycolate (Type A), Povidone(K-30), Magnesium Stearate.  
*Tablet coating:* Hypromellose 2910 (E464), Macrogol 6000 (E1521), Titanium Dioxide (E171)

##### What Propranolol looks like and contents of the pack

Film-coated tablet.

##### Propranolol 10mg film-coated tablets

White to off-white, Round, biconvex film coated tablets debossed with 'I' on one side and '10' on the other side. The diameter is 5.0 mm.

##### Propranolol 40mg film-coated tablets

White to off-white, Round, biconvex film coated tablets debossed with 'I 40' on one side and quadra section on the other side. The diameter is 8.0 mm.

The tablet can be divided into equal doses.

Propranolol film-coated tablets are available in white, opaque PVC – Aluminium foil blister pack of 28 film-coated tablets.

##### Marketing Authorisation Holder

Milpharm Limited, Ares Block, Odyssey Business Park, West End Road, Ruislip HA4 6QD, United Kingdom.

##### Manufacturer

APL Swift Services (Malta) Limited HF26, Hal Far Industrial Estate, Hal Far, Birzebbugia, BBG 3000 Malta

or

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or

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