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

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:Hypertension (high blood pressure)
- Angina (chest pain)
- Some arrythmias (disorders of heart rhythm)
- Protection of the heart after a myocardial infarction (heart attack)
- Migraine
- Essential tremor (involuntary and rhythmic shaking)
- Certain thyroid conditions (thyrotoxicosis and hyperthyroidism, which are caused by an overactive thyroid gland)
- Hypertrophic cardiomyopathy (thickened heart muscle)
- Phaeochromocytoma (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

Do not take Propranolol tablets 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
- have had a shock caused by heart problems
- have 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 unever heart rate
- have an 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:
- 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.
- 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 heart problems.
- Suffer from muscle weakness (myasthenia gravis)
- 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').

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 medicines and some medicines can have an effect on Propranolol.

Propranolol should not be used in combination with calcium channel blockers with negative inotropic effects (e.g. verapamil, diltiazem), as it can lead to an exaggeration of these effects. This may result in severe hypotension and bradycardia.

Other medicines which can cause problems when taken together with your medicine:

- Nifedipine, nisoldipine, nicardipine, isradipine, lacidipine (used to treat hypertension or angina)
- Lidocaine (local anesthetic)
- Disopyramide, quinidine, amiodarone , propafenone and glycosides (to treat heart problems)
- 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)

- Fingolimod (for treating multiple sclerosis)
- Fluvoxamine and barbiturates (to treat anxiety and insomnia)
- MAO inhibitors (to treat depression)

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.

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.

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.

Pregnancy:
The use of this medicine is not recommended during pregnancy, unless your doctor considers it essential.

Breastfeeding:
Breastfeeding is not recommended when taking this medicine.

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 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
The following table shows the recommended dosages for an adult:

	Recommended dose	Total daily dosage (Maximum)
Hypertension (high blood pressure)	Initially 40 mg two or three times daily, which may be increased by 80 mg per day at weekly intervals.	160 mg to 320 mg
Angina (chest pains) and tremor	Initially 40 mg two to three times daily, which may be increased by 40 mg per day at	120 mg to 240 mg

	weekly intervals.	
Protection of the heart after a heart attack	Initially 40 mg four time a day and after a few days changes to 80mg twice a day	160 mg
Migraine	Initially 40 mg two to three times daily, which may be increased by 40 mg per day at weekly intervals.	80 mg to 160 mg
Arrythmias (disorders of heart rhythm), hyperthyroidism and thyrotoxicosis (certain thyroid conditions) and hypertrophic cardiomyopathy (thickened heart muscle)	10 to 40 mg three or four times daily	120 mg to 160 mg
Phaeochromocytoma	Before an operation: 60 mg daily Non-operable treatment dose: 30 mg daily	30 mg to 60 mg
Liver disease due to high blood pressure	Initially 40mg twice daily, increasing to 80mg twice daily	160 mg to 320 mg

Pediatric population
Propranolol can also be used to treat children with migraine and arrythmias:
- For migraine the dose under the age of 12 is 20 mg two or three times daily and the adult dose for children 12 years or older.
- For arrythmias the dosage will be adjusted by the doctor according to the child's age or weight.

Older people
Older people should be started with the lowest dose. The optimum dose will be individually determined by the doctor.

Liver or kidney failure
The optimum dose will be individually determined by the doctor.

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.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 overdose. If you have accidently 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 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
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, pharmacist or nurse.

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 syndrome)
- Disturbed sleep/nightmares
- Fatigue
- Breathlessness

Uncommon (may affect up to 1 in 100 people):
- Nausea, vomiting and diarrhoea

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 or asthmatic complaints
- Heart failure, worsening of heart problems
- Swelling of the skin which may occur in the face, tongue, larynx, abdomen, or arms and legs (angioedema)
- Dizziness, particularly on standing up
- Worsening of your blood circulation, if you already suffer from poor circulation
- Hair loss (Alopecia)
- Mood changes
- Confusion
- Memory loss
- Psychosis or hallucinations (disturbances of the mind)
- Paraesthesia (an abnormal sensation, typically tingling or pricking ('pins and needles')
- Disturbances of vision
- Dry eyes
- Skin rash, including worsening of psoriasis
- Your medicine may alter the number and types of your blood cells such as reduce the number of platelets (thrombocytopaenia) in your blood which may make you bruise and bleed more easily.
- Purple spots on the skin (purpura)

Very rare (may affect up to 1 in 10,000 people):
- Severe muscle weakness (myasthenia gravis).
- 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.
- 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 eya also called 'pink eye')
- Depression
- Severe and dangerous lowered white blood cell count (agranulocytosis)
- Worsening of angina pectoris (chest pains)

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 Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

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:

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