Package leaflet: Information for the user

Propranolol Thame 5mg/5ml Oral Solution
Propranolol Thame 10mg/5ml Oral Solution
Propranolol Thame 40mg/5ml Oral Solution
Propranolol Thame 50mg/5ml Oral Solution
(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.

The name of your medicine is Propranolol Thame 5mg/5ml, 10mg/5ml, 40mg/5ml and 50mg/5ml Oral Solution but it will be referred to as 'Propranolol' throughout this leaflet.

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 is one of a group of drugs 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 arrythmias (disorders of heart rhythm)
- Protection of the heart after a myocardial infarction (heart attack)
- Prevention of migraine
- Essential tremor, anxiety
- Certain thyroid conditions (such as thyrotoxicosis, which is 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

If you have ever had asthma or wheezing, do not take your Propranolol. Go back to your doctor or pharmacist.

Do not take Propranolol if:
- You are allergic to propranolol or any of the other ingredients listed in section 6.

Warnings and precautions
Talk to your doctor, pharmacist or nurse 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 phaeochromocytoma (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, pharmacist or nurse 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 as Propranolol may hide the symptoms of thyrotoxicosis
- Have kidney or liver problems (including cirrhosis of the liver) 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, pharmacist or nurse if you are taking, have recently taken or might take any other medicines. This is because some medicines can affect the way Propranolol works or Propranolol can affect how other medicines work. These medicines include the following:
- 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, drinks and alcohol
Alcohol may affect how this medicine works.

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

Propranolol contains:
Methyl parahydroxybenzoate (E218): May cause allergic reactions (possibly delayed).
Liquid Maltitol (E965): 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 product contains 6.3mg/5ml **propylene glycol** (E1520) as an ingredient necessary for the medicine to work properly. Talk to your doctor or pharmacist before giving this medicine to your baby if he/she is less than 4 weeks old.

3. How to take Propranolol

Always take this medicine exactly as your doctor or pharmacist has told you. Your doctor will have decided how much Propranolol you need to take each day depending on your condition. Follow your doctor's instructions about when and how to take your medicine. Ask your doctor or pharmacist if you are not sure.

The following table shows the recommended total daily dosages for an adult:

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

Older people may be started on a lower dose.

It is recommended to use the lower strength (5mg/5ml) of Propranolol Oral Solution when a lower dose (<5mg) is required.

Method of administration:
This medicinal product must be taken orally.
Use the measuring syringe or cup provided in the pack to deliver the required dose.

If you take more Propranolol than you should
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.

Contact your doctor or pharmacist straight away or go to your nearest hospital casualty department. Always take any remaining medicine, 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 your medicine, take your dose when you remember and then take your next dose at the usual time. Do not 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, Propranolol 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, 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 occur less than 1 in 10,000 patients)
- 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.

Do not be alarmed by this list of possible events. You may not have any of them.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any side effects not listed in this leaflet.

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 ADR Reporting at www.medicinesauthority.gov.mt/adrportal. By reporting adverse reactions 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 Propranolol after the expiry date which is stated on the carton or bottle label after 'Exp'. The expiry date refers to the last day of that month.
- This medicinal product does not require any special storage conditions.
- Discard 90 days after first opening.
- Do not use this medicine if you notice that the solution becomes discoloured or shows any signs of deterioration. Seek the advice of your pharmacist.
- Do not throw away any medicine via waste water or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Propranolol contains
Each 5ml of oral solution contains 5mg propranolol hydrochloride.
Each 5ml of oral solution contains 10mg propranolol hydrochloride.
Each 5ml of oral solution contains 40mg propranolol hydrochloride.
Each 5ml of oral solution contains 50mg propranolol hydrochloride.

The other ingredients are methyl parahydroxybenzoate (E218), citric acid monohydrate (E330), liquid maltitol (E965), orange flavour (containing propylene glycol (E1520)) and purified water.

What Propranolol looks like and contents of the pack
Propranolol is a clear, colourless oral solution with an orange flavour supplied in an amber glass bottle with tamper-evident child resistant plastic cap with a 5ml oral syringe with 0.1ml graduation marks and a 30ml cup with 5ml graduation with intermediate graduation at 2.5ml and 7.5ml for measuring and administering the dose and a bottle adaptor.

Propranolol is supplied in bottles containing 150ml solution.

POM

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