Package leaflet: Information for the patient

Propranolol hydrochloride 10 mg orodispersible tablets
Propranolol hydrochloride 40 mg orodispersible 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 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 hydrochloride 10 mg and 40 mg orodispersible tablets. It will be called Propranolol hydrochloride for ease from here

What is in this leaflet

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

1. What Propranolol hydrochloride is and what it is used for

The name of your medicine Propranolol hydrochloride orodispersible tablet. The active ingredient is propranolol hydrochloride. Propranolol hydrochloride is produced as orodispersible tablets in two different strengths. Each orodispersible tablet contains 10 mg or 40 mg of propranolol hydrochloride.

Propranolol hydrochloride 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 hydrochloride 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)
- 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 hydrochloride

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

Do not take Propranolol hydrochloride:

- If you are allergic 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 hydrochloride.

Propranolol hydrochloride 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 hydrochloride

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

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

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Propranolol hydrochloride 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 hydrochloride 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 hydrochloride 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 hydrochloride.

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 hydrochloride. 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.

Propranolol hydrochloride contains aspartame
Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

Propranolol hydrochloride contains sodium
This medicinal product contains less than 1 mmol (23 mg) sodium per orodispersible tablet, that is to say essentially 'sodium-free'.

3. How to take Propranolol hydrochloride

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The tablet should be placed on the tongue and allowed to disintegrate before swallowing with or without water, according to patient preference. Your doctor will have decided how many Propranolol hydrochloride 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
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 hydrochloride 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.

The score line is not intended for breaking the tablet.

If you take more Propranolol hydrochloride than you should

Propranolol hydrochloride 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 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 hydrochloride
If you forget to take your medicine, take your dose when 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 hydrochloride
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, 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 hydrochloride 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 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 hydrochloride

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. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

If your doctor decides to stop treatment, return any leftover tablets to your pharmacist. Only keep them if the doctor tells you to.

6. Contents of the pack and other information

What Propranolol hydrochloride contains:
The active ingredient is propranolol hydrochloride. Propranolol hydrochloride is produced as orodispersable tablets in two different strengths. Each tablet contains 10 mg or 40 mg of propranolol hydrochloride.

Your medicine also contains the following inactive ingredients:

Mannitol (E421), Cellulose, Microcrystalline (E460), Sodium Starch Glycolate, Aspartame (E 951), Magnesium stearate (E572).

Orange flavor contains - Acacia gum (E 414), Flavoring preparations, BHA (Butylated hydroxyanisole) (E 320).

What Propranolol hydrochloride look like and contents of the pack
Propranolol hydrochloride 10 mg and 40 mg orodispersible tablets are produced in blister packs containing 28, 30, 56, and 60 tablets and HDPE Bottle packs with 100 tablets.
Not all pack sizes may be marketed.

Propranolol hydrochloride 10 mg orodispersible tablets are white to off white, round, flat uncoated tablet, debossed with "10" on one side and break line on other side with approximately 6.00 mm diameter.

Propranolol hydrochloride 40 mg orodispersible tablets are white to off white, round, flat uncoated tablet, debossed with "40" on one side and break line on other side with approximately 11.00 mm diameter.

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