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|---------------|---|---|---|--|
| Product:      | <b>Propranolol 10 mg,<br/>40 mg &amp; 80 mg Tablets</b> | Printing Colours:   | Non-Printing Colours:   |   |
| MA Holder:    | <b>Chelonia</b>   |  Black |  Profile |  |
| PL No.:       | <b>33414/0095-0096-0097</b>                             | Dimensions:   | <b>148 x 297 mm</b>   |  |
| Pack Size:    | <b>All</b>  | AW Code:  | <b>CL0095-0096-0097/O/PIL/CL3</b>   |  |
| Livery:       | <b>Chelonia</b>   | Bar Code:   | -   |  |
| Manufacturer: | -   | Font & Size:  | <b>Arial Narrow, 8.25 pt</b>  |  |
| Market:       | <b>UK</b>   | Created By:   | <b>MKumbhar</b>   |  |
| Component:    | <b>Leaflet</b>  | Version:  | <b>0.3</b>  |  |
|               |   |   |   | Final Preparation Date For Submission: <b>12/12/2025</b><br>Packing Site Technical Approval: <b>00/00/0000</b><br>Authority Approval Date: <b>00/00/0000</b><br>Latest Implementation Deadline: <b>00/00/0000</b><br>Print Proof Approval: <b>00/00/0000</b> |

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# Propranolol 10 mg, 40 mg & 80 mg 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.

## 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

The name of your medicine is Propranolol. The active ingredient is propranolol. Propranolol is produced as film-coated tablets in three different strengths. Each tablet contains 10 mg, 40 mg or 80 mg of propranolol hydrochloride. 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:

- chest pain (angina pectoris)
- high blood pressure (hypertension)
- essential tremor, anxiety
- some arrhythmias (disorders of heart rhythm)
- hypertrophic cardiomyopathy (thickened heart muscle)
- protection of the heart after a myocardial infarction (heart attack)
- phaeochromocytoma (high blood pressure due to a tumour usually near the kidney) where an alpha-blocker is also prescribed
- help prevent additional heart attacks
- certain thyroid conditions (such as thyrotoxicosis, which is caused by an overactive thyroid gland)
- prevention of migraine
- 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 Propranolol. Go back to your doctor or pharmacist.**

**Do not take Propranolol:**

- if you are allergic to propranolol 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 tablets.

Propranolol should not be taken by people who;

- have any of the following heart problems:
  - heart failure which is not under control (signs include breathlessness and swollen ankles)
  - second- or third-degree heart block (a condition which may be treated with a pacemaker)
  - have a heart weakness or first-degree heart block
  - very slow or very uneven heart beats
  - very low blood pressure (hypotension) which can make you feel dizzy or light-headed, severe blood circulation problems (which may cause your fingers and toes to tingle or turn pale or blue)
  - chest pain that happens when you are resting rather than during exercise (Prinzmetal's angina)
  - have a sudden and rapid fall in blood pressure (cardiogenic shock)
  - a problem (common in the elderly) related to poor control of the working of the heart (sick sinus syndrome)
- have not been eating (fasting) for a long period of time or if your blood has become too acidic (metabolic acidosis).
- people who have phaeochromocytoma (high blood pressure due to a tumour usually near the kidney) which

is not being treated.

- have or sometimes get low blood sugar (hypoglycaemia). This can happen if you are not eating well, have long-term liver disease or have diabetes.

Your doctor will know about these conditions. If you have one of these conditions, make sure your doctor knows about this before you take Propranolol tablets.

Talk to your doctor or pharmacist before taking Propranolol tablets.

Tell your doctor **before** you take this medicine if you:

- suffer from unstable angina (non exercise-induced sharp chest pain).
- get allergic reactions to such things as insect stings
- have an overactive thyroid gland (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 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 (see section 4 "Possible side effects").
- 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 medicines. The drugs which can cause some problems when taken together with your medicine are:

- insulin (to treat diabetes)
- disopyramide
- amiodarone and propafenone (for irregular heartbeats)
- lidocaine
- verapamil
- diltiazem
- nifedipine
- nisoldipine
- nicardipine
- isradipine
- lacidipine (which are used to treat hypertension or angina)
- digoxin (for heart failure)
- adrenaline (a heart stimulant)
- ibuprofen and indomethacin (for pain and inflammation)
- chlorpromazine and thioridazine (for certain psychiatric disorders)
- theophylline (for asthma)
- warfarin (to thin the blood) and hydralazine (for hypertension)
- quinidine
- cimetidine (for stomach problems)
- rifampicin (for the treatment of tuberculosis)
- ergotamine, dihydroergotamine or rizatriptan (for migraine)

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 operate machinery. However, some people may occasionally feel dizzy or tired while taking Propranolol tablets. 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 contains Lactose

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 has told you. Check with your doctor or pharmacist if you are not sure. Propranolol tablets should be swallowed with a drink of water. Your doctor will have decided how many Propranolol 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           |
| 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 irregular heartbeats, phaeochromocytoma, thyrotoxicosis, Fallot's tetralogy, migraine. The dosage will be adjusted by the doctor according to the child's age and weight.

Older people may be started on a lower dose.

#### **If you take more Propranolol tablets 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. Overdose causes difficulty breathing, low blood pressure, drowsiness, fits, dilated pupils, an excessively slowed heartbeat with symptoms such as dizziness, sickness, confusion, hallucinations, body spasms, breathlessness on exertion, fainting or coma. Overdose could result in heart attack.

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

If you forget to take your medicine, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose (two doses at the same time) to make up for a forgotten dose. If you are worried, ask your doctor or pharmacist for advice.

#### **If you stop taking Propranolol tablets**

Do not stop taking this 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**

If you get any of the following side effects, see your doctor or go to the nearest hospital emergency department straight away:

- difficulty in breathing, especially if you have a history of asthma, wheezing or other lung diseases.

If you get any of the following side effects, stop taking Propranolol tablets and tell your doctor as soon as possible:

- slowing of the heart beat or worsening of heart failure (signs include breathlessness and swollen ankles)
- low blood pressure (hypotension) which can make you feel dizzy or lightheaded when standing quickly
- feeling dizzy or faint, and worsening of breathing (called 'heart block')
- poor blood circulation making the fingers and toes cold, numb and pale (Raynaud's phenomenon), this can lead to cramp-like pains in the lower leg
- bleeding or bruising more easily or purplish marks on the skin, sore throat, fever, frequent infections. These symptoms may indicate changes in the levels of your blood cells
- low blood sugar (hypoglycaemia) 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 long-term liver disease. Signs include weakness, headache, feeling hungry, visual disturbances, mood changes and fits (seizures)
- swelling of the face, lips, throat or tongue.

Tell your doctor or pharmacist if you notice any of the following side effects:

#### **Common (may affect up to 1 in 10 people)**

- nightmares or difficulty sleeping
- feeling tired or weak

#### **Uncommon (may affect up to 1 in 100 people)**

- feeling sick (nausea), being sick (vomiting) or diarrhoea

#### **Rare (may affect up to 1 in 1,000 people)**

- strange sounds and visions (hallucinations), loss of touch with reality (psychoses), mood changes, feeling confused, memory loss
- tingling or numbness in the hands and feet
- dry eyes, changes in eyesight, hair loss
- skin rashes or worsening of the skin problem 'psoriasis'

#### **Very rare (may affect up to 1 in 10,000 people)**

- new muscle weakness or a disease of the muscles (called 'myasthenia gravis') getting worse
- 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)**

- depression

#### **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.** Your medicine could harm them.

Store below 25°C. Store in the original package or container, and keep the container tightly closed, in order to protect from light and moisture.

Do not use the tablets after the expiry date stated on the pack. 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 contains**

The active substance is propranolol hydrochloride. Each film-coated tablet contains either 10 mg, 40 mg or 80 mg of propranolol hydrochloride.

The other ingredients are; lactose monohydrate, gelatin, stearic acid, magnesium stearate, ethylcellulose, hypromellose, diethylphthalate, colours (titanium dioxide E171, carmine E120), and beeswax yellow.

#### **What Propranolol tablets look like and contents of the pack**

The 10 mg tablets are pink, round, film-coated tablets engraved ANGILOL 10 on one side. The diameter of each film-coated tablet is approximately 6.5 mm.

The 40 mg tablets are pink, round, film-coated tablets engraved ANGILOL 40 on one side. The diameter of each film-coated tablet is approximately 8.5 mm.

The 80 mg tablets are pink, round, film-coated tablets engraved ANGILOL 80 on one side. The diameter of each film-coated tablet is approximately 9.5 mm.

Propranolol tablets are available in containers of 50, 100, 250, 500 and 1,000 tablets, and in blister packs of 28 and 56 tablets. Not all pack sizes may be marketed.

#### **Marketing Authorisation Holder**

Chelonia Healthcare Limited,  
11 Boumpoulinas, 3rd Floor,  
1060 Nicosia, Cyprus

#### **Manufacturer**

DDSA Pharmaceuticals Limited,  
84 Pembroke Road  
London, W8 6NX, UK

For more information about this product, please contact the Marketing Authorisation Holder.

**This leaflet was revised in 12/2025.**

CL0095-0096-0097/O/PIL/CL3