

PACKAGE LEAFLET: INFORMATION FOR THE USER

Propranolol Tablets 10mg

Propranolol Tablets 40mg

(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 Tablets are and what they are used for
2. What you need to know before you take Propranolol Tablets
3. How to take Propranolol Tablets
4. Possible side effects
5. How to store Propranolol Tablets
6. Contents of the pack and other information

1. What Propranolol Tablets are and what they are used for

The name of your medicine is Propranolol tablets 10mg and Propranolol tablets 40mg. The active ingredient is propranolol. Propranolol tablets is produced as film-coated tablets. Each tablet contains 10 mg or 40 mg of propranolol hydrochloride.

Propranolol is one of a group of drugs called beta blockers. It has effects on the heart and circulation and on other parts of the body.

Propranolol can be used for many conditions including:

- hypertension (high blood pressure),
- angina (chest pains),
- 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.

You must talk to a doctor if you do not feel better or if you feel worse

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PROPRANOLOL TABLETS

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 to propranolol or any of the other ingredients of this medicine (listed in section 6).
- have a history of asthma or wheezing.
- have untreated/uncontrolled heart failure or are in shock caused by heart problems (cardiogenic shock).
- suffer with heart conduction or rhythm problems (second or third-degree heart block or sick sinus syndrome).
- have a slow heart rate (bradycardia).
- have a low blood pressure.
- suffer from severe blood circulation problems (which may cause your fingers toes to tingle or turn pale or blue).
- suffer from diabetes mellitus (low blood sugar levels may be hidden by this medicine) and increased acidity of the blood (metabolic acidosis).
- are on a strict fasting diet.
- suffer from a tight, painful feeling in the chest in period of rest (Prinzmetal's angina).
- suffer from untreated pheochromocytoma (high blood pressure due to a tumour near the kidney). Suffer from chronic liver disease, portal hypertension, diabetes, starvation and malnutrition.
- suffer from rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption.

Warnings and precautions

Talk to your doctor or pharmacist before taking propranolol tablets if you:

- get allergic reactions to such things as insect stings.
- you have signs of heart failure which have been controlled or whose cardiac reserve is poor.
- 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 this condition.

- suffer from unstable angina (non-exercise-induced sharp chest pain).
- 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.
- have a history of allergic reactions.
- suffer from muscle weakness (myasthenia gravis).
- have a heart weakness or first-degree heart block.
- have kidney or liver disease.
- suffer from blood circulation problems (which may cause your fingers and toes to tingle or turn pale or blue).
- have symptoms of hyperthyroidism (increased appetite, weight loss, sweating).
- suffer with or have a history of psoriasis.
- suffer from Raynaud's disease (cold sensations in fingers and toes) or intermittent claudication (narrowing of arteries in the legs causing pain on walking).
- you smoke or are elderly.

Other medicines and Propranolol tablets

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines. Propranolol tablets 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 take together with your medicine are:

- Verapamil
- Diltiazem
- Nifedipine
- Nisoldipine
- Nicardipine
- Isradipine
- Lacidipine, (which are used to treat hypertension or angina)
- Disopyramide
- Lidocaine
- Insulin
- Amiodarone or propafenone (for irregular heartbeats)
- 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 high blood pressure 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 the clonidine, your doctor will give you careful instructions on how to do it.

Propranolol Tablets with food, drink and alcohol

Alcohol may affect how this medicine works.

Pregnancy and Breast feeding

As with all drugs propranolol should not be given during pregnancy unless its use is essential. Breastfeeding is not recommended during administration of propranolol tablets.

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.

Operations

If you go into hospital for 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.

Propranolol contains lactose

Propranolol tablets 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 TABLETS

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 the 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 from 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.

The score line is not intended for breaking the tablet.

If you take more Propranolol Tablets than you should:

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.

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 forget to take Propranolol Tablets:

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 Tablets:

Do not stop taking your medicine without talking to your doctor first. In some cases, it may be necessary to stop taking the medicines 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.

Stop treatment and contact a doctor at once if you have the following symptoms of an:

- intolerance to propranolol tablets such as slow heart and low blood pressure causing dizziness, light headedness, fainting or blurred vision
- allergic reaction such as itching, difficulty breathing or swelling of the face, lips throat or tongue.

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 (thrombocytopenia)
- 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 tablets 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 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 TABLETS

Keep your medicine in a safe place 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. Securitainers:

Do not store your medicine above 25°C

Store in the original container

28 tablets blister packs:

No special storage conditions required.

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 Tablets contain**

The active substance is propranolol hydrochloride. Each tablet contains 10 mg or 40 mg of propranolol hydrochloride. The other ingredients are Lactose, Talc, Stearic Acid, Magnesium Stearate, Hypromellose (E464), Polyethylene Glycol (E1521), Titanium Dioxide (E171) and Carmine (E120). Propranolol tablets 40mg also contains microcrystalline cellulose.

What Propranolol Tablets look like and contents of the pack

Propranolol Tablets 10mg: Are pink, film-coated, bi-convex tablets embossed 'P10' on one face.

Propranolol Tablets 40mg: Are Pink film-coated biconvex tablets with break line on face and embossed P 40 on the other

The score line is not intended for breaking the tablet.

Securitainers: 20, 50, 500 and blister pack 28 Tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Noumed Life Sciences Limited,
Noumed House, Maidenhead,
SL6 2RB, United Kingdom

This leaflet was last revised in August 2020

Other sources of information:

To listen to or request a copy of this leaflet in braille, large print or audio please call, 020 33998960 (UK only)

Please be ready to give the following information:

Product name: Reference number:

Propranolol Tablets 10 mg PL 44041/0115

Propranolol Tablets 40 mg PL 44041/0116



Black

Signature of Author:				Font Type & Size	Main: Helvetica	
Signature of RA:					Body: Helvetica	
				Title: Art Work Approval Form		
Product	Propranolol Tablets combined PIL			Specification:		
Customer	NOUMED LIFE SCIENCES LIMITED, UK					
Reason for Issue	combination PIL			Colours:	Black	
PL No.	44041/0115 44041/0016		Pharmacode No.		Dimensions:	180 x 300 mm
	Item Code	LPRO04/00	Layout No.:		No. of Folds (only for PIL)	

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1. WHAT PROPRANOLOL TABLETS ARE AND WHAT THEY ARE USED FOR

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- essential tremor, anxiety,
- certain thyroid conditions (such as thyrotoxicosis, which is caused by an overactive thyroid gland),
- hypertrophic cardiomyopathy (thickened heart muscle),
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- bleeding in the oesophagus caused by high blood pressure in the liver.

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- suffer with heart conduction or rhythm problems (second or third-degree heart block or sick sinus syndrome).
- have a slow heart rate (bradycardia).
- have a low blood pressure.
- suffer from severe blood circulation problems (which may cause your fingers toes to tingle or turn pale or blue).
- suffer from diabetes mellitus (low blood sugar levels may be hidden by this medicine) and increased acidity of the blood (metabolic acidosis).
- are on a strict fasting diet.
- suffer from a tight, painful feeling in the chest in period of rest (Prinzmetal's angina).
- suffer from untreated pheochromocytoma (high blood pressure due to a tumour near the kidney). Suffer from chronic liver disease, portal hypertension, diabetes, starvation and malnutrition.
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Warnings and precautions

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- you have signs of heart failure which have been controlled or whose cardiac reserve is poor.
- 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 this condition.

- suffer from unstable angina (non-exercise-induced sharp chest pain).
- 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.
- have a history of allergic reactions.
- suffer from muscle weakness (myasthenia gravis).
- have a heart weakness or first-degree heart block.
- have kidney or liver disease.
- suffer from blood circulation problems (which may cause your fingers and toes to tingle or turn pale or blue).
- have symptoms of hyperthyroidism (increased appetite, weight loss, sweating).
- suffer with or have a history of psoriasis.
- suffer from Raynaud's disease (cold sensations in fingers and toes) or intermittent claudication (narrowing of arteries in the legs causing pain on walking).
- you smoke or are elderly.

Other medicines and Propranolol tablets

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines. Propranolol tablets 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 take together with your medicine are:

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- Adrenaline (a heart stimulant)
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- 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 high blood pressure 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 the clonidine, your doctor will give you careful instructions on how to do it.

Propranolol Tablets with food, drink and alcohol

Alcohol may affect how this medicine works.

Pregnancy and Breast feeding

As with all drugs propranolol should not be given during pregnancy unless its use is essential. Breastfeeding is not recommended during administration of propranolol tablets. 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.

Operations

If you go into hospital for 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.

Propranolol contains lactose

Propranolol tablets 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 TABLETS

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:

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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 from 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. The score line is not intended for breaking the tablet.

If you take more Propranolol Tablets than you should:

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. 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 forget to take Propranolol Tablets:

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 Tablets:

Do not stop taking your medicine without talking to your doctor first. In some cases, it may be necessary to stop taking the medicines 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.

Stop treatment and contact a doctor at once if you have the following symptoms of an:

- intolerance to propranolol tablets such as slow heart and low blood pressure causing dizziness, light headedness, fainting or blurred vision
- allergic reaction such as itching, difficulty breathing or swelling of the face, lips throat or tongue.

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
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- Hair loss
- Mood changes
- Confusion
- Memory loss
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- Tingling of the hands
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- Dry eyes
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Do not store your medicine above 25°C

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28 tablets blister packs:

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6. CONTENTS OF THE PACK AND OTHER INFORMATION**What Propranolol Tablets contain**

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What Propranolol Tablets look like and contents of the pack

Propranolol Tablets 10mg: Are pink, film-coated, bi-convex tablets embossed 'P10' on one face.

Propranolol Tablets 40mg: Are Pink film-coated biconvex tablets with break line on face and embossed P 40 on the other

The score line is not intended for breaking the tablet.

Securitainers: 20, 50, 500 and blister pack 28 Tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

 Noumed Life Sciences Limited,
Noumed House, Maidenhead,
SL6 2RB, United Kingdom

This leaflet was last revised in August 2020

Other sources of information:

To listen to or request a copy of this leaflet in braille, large print or audio please call, 020 33998960 (UK only)

Please be ready to give the following information:

Product name: Reference number:

Propranolol Tablets 10 mg PL 44041/0115

Propranolol Tablets 40 mg PL 44041/0116

LPRO05/00



Black

Signature of Author:				Font Type & Size	Main: Helvetica	
Signature of RA:					Body: Helvetica	
				Title: Art Work Approval Form		
Product	Propranolol Tablets combined PIL			Specification:		
Customer	NOUMED LIFE SCIENCES LIMITED, UK					
Reason for Issue	combination PIL - new size			Colours:	Black	
				Dimensions:	140 x 330 mm	
PL No.	44041/0115 44041/0016	Pharmacode No.		No. of Folds (only for PIL)		
Item Code	LPRO05/00	Layout No.:				