

PATIENT INFORMATION LEAFLET
Propranolol 160mg & 80mg Sustained Release Capsules
(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, please 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 this medicine is and what it is used for
2. What you need to know before you take this medicine
3. How to take this medicine
4. Possible side effects
5. How to store this medicine
6. Contents of the pack and other information

1 What this medicine is and what it is used for

Propranolol belongs to a group of medicines called beta-blockers, which help slow the heartbeat and relax the blood vessels. This reduces blood pressure and the heart's demand for oxygen.

Your doctor may have given you propranolol before but under a different brand name. The effect will be the same.

This medicine is used to treat the following conditions:

- High blood pressure (hypertension).
- Pains in the chest (angina).
- Shaking of the hands, head and face (essential tremor).
- Management of anxiety.
- Overactive or enlarged thyroid (thyrotoxicosis or graves' disease).
- Recurrent migraine attacks.
- Bleeding in the stomach and intestines caused by high blood pressure in the belly region and lower throat.

2 What you need to know before you take this medicine

Do not take Propranolol if:

- **You have a history of breathing difficulties, wheezing or asthma.**
- You are allergic to Propranolol, other beta-blockers or any of the other ingredients of this medicine (see section 6 "Contents of the pack and other information").
- You have heart problems.
- You sometimes suffer from low blood sugar levels (hypoglycaemia) e.g. due to not having eaten for a long period of time.
- You have more acid than normal in your blood (metabolic acidosis).
- You have chest pains when at rest (prinzmetal's angina).
- You have an untreated tumour in your kidneys (phaechromocytoma).
- You have a very slow heart rate (bradycardia).
- You have low blood pressure (hypotension).
- You have severe circulation problems.

Warnings and precautions

Talk to your doctor before taking this medicine if:

- Your heart has difficulty pumping blood around your body (low cardiac reserve).
- Your heartbeat slows to less than 50–55 beats per minute whilst resting.
- You have diabetes as this medicine may delay your response to low blood sugar treatment.
- You have a poor flow of blood to your heart (ischaemic heart disease).

- You have an irregular heartbeat (first degree heart block).
- You have circulatory problems which are not severe such as your toes and fingers go numb and pale (raynaud's syndrome) or you sometimes limp (intermittent claudication) as these disorders may become worse during treatment.
- You have any liver problems (such as cirrhosis).
- You have kidney problems.
- You have a history of severe allergic reaction which can cause difficulty in breathing or dizziness (anaphylactic reaction).
- You are allergic to sulfur dioxide (rare).
- You are stopping treatment as this must be done gradually (see section 3).
- You are older as you may need to start on a lower dose.
- You have thyrotoxicosis (a condition caused by an overactive thyroid gland). Your medicine may mask the symptoms of thyrotoxicosis.
- If you are taking verapamil or diltiazem [calcium channel blockers] (see "Other medicines..." section).

Other medicines and Propranolol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those obtained without a prescription. This includes herbal medicines.

Some medicines may affect the way Propranolol works, in particular, the following:

- Cimetidine, for stomach ulcers and indigestion.
- Hydralazine, for high blood pressure.
- Fluvoxamine, used to treat depression and Obsessive Compulsive Disorder (OCD).
- Alcohol (see 'Taking this medicine with alcohol' section).

With some medicines, side effects can occur when taken together with Propranolol. These include:

- Adrenaline, for emergency treatment of allergic reaction (anaphylaxis) or the heart stops (cardiac arrest) or other sympathomimetic agents.
- Medicines for heart failure such as digitoxin, digoxin (digitalis glycosides).
- Ergotamine, for migraines.
- Indomethacin, for arthritis and other prostaglandin inhibiting drugs, such as ibuprofen.
- Medicines for irregular heartbeat, such as disopyramide, quinidine and amiodarone.
- Lidocaine, used as a local anaesthetic or for an irregular heartbeat.
- Medicines for depression, such as moclobemide, (MAO inhibitors).
- Nifedipine, for high blood pressure and chest pains (angina).
- Medicines for depression, such as amitriptyline (tricyclic antidepressants).
- Medicines for sleeping difficulties, such as amobarbital (barbiturates).
- Other medicines for high blood pressure such as ACE inhibitors.
- Chlorpromazine for anxiety, feeling sick (nausea), being sick (vomiting) or mental disorders and other phenothiazines, such as trifluoperazine.
- Rizatriptan, used to treat migraine headaches.
- Angiotensin-II Antagonists, used to treat high blood pressure e.g. telmisartan.
- Aldesleukin, to treat some cancers.
- Alprostadil, for sexual problems.
- Corticosteroid e.g. hormone replacement.
- Moxisylyte, to treat poor circulation.
- Muscle relaxants, used to treat multiple sclerosis.
- The contraceptive pill.
- Parasympathomimetics e.g. pyridostigmine used to treat myasthenia gravis.

Special care should be taken with the following medicines;

- Clonidine, for high blood pressure and migraine. If Propranolol is used instead of clonidine or both medicines are used together, you must take advice from your doctor.
- Verapamil or diltiazem, medicines for high blood pressure or chest pains (angina).
- Medicines for the treatment of diabetes, such as insulin and metformin.
- Tropisetron, for nausea and vomiting (feeling and being sick).
- Xamoterol, a heart stimulant.

The dose of Propranolol may need to be adjusted if you take the following:

- Propafenone, for irregular heartbeat
- Rifampicin, antibiotic used for various infections, in particular tuberculosis.
- Theophylline, for asthma
- Warfarin, for thinning the blood
- Thioridazine, for mental illness
- Calcium channel blockers for high blood pressure or chest pain), such as nisoldipine, nicardipine, isradipine and lacidipine
- Thyroxine, for certain thyroid disorders

Having an anaesthetic or a blood test

You must tell the medical staff that you are taking Propranolol if you are going to have surgery under anaesthetic or a blood test.

- **Anaesthetics** – Anaesthetics may interfere with this medicine.
- **Blood test** – This medicine may interfere with the results obtained.

Taking this medicine with alcohol

It is recommended that you do not drink alcohol whilst being treated with Propranolol.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking Propranolol.

Pregnancy

You should not take this medicine unless essential.

Breast-feeding

If you are breast-feeding, the use of this medicine should be avoided as it is passed into breast milk.

Driving and using machines

Propranolol is unlikely to affect your ability to drive or operate machinery. Occasionally you may feel a bit dizzy or more tired than normal. If this happens, do not drive or operate machinery and consult your doctor or pharmacist.

This medicine contains E220 sulfur dioxide

May rarely cause severe allergic (hypersensitivity) reactions and difficulty in breathing or wheezing (bronchospasm).

This medicine contains sugar-starch neutral microgranules

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 this medicine

Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- These capsules are to be taken orally.
- Each capsule should be taken at a regular time each day (morning or evening), unless instructed differently.

Warning for diabetics

Diabetics should not go for long periods without food whilst taking Propranolol. Ask your doctor for advice if you have missed several meals for any reason.

One of the actions of this medicine is to slow the heart. This could mask an increase in the heart rate which may be a warning sign of low blood sugar levels (hypoglycaemia). In addition, it may delay the recovery of blood glucose to normal levels after taking insulin.

High blood pressure (hypertension)

- The usual recommended starting dose is one 160mg capsule daily.
- If necessary, the dose can be increased in 80mg increments until an adequate response is achieved (up to a maximum of 320mg daily).

Migraine

Chest pains (angina)

Shaking of the hands, head and face (essential tremor)

Overactive or enlarged thyroid (thyrotoxicosis or graves' disease)

- The usual recommended starting dose is one 80mg capsule daily.
- If necessary, the dose can be increased in 80mg increments up to a maximum of 240mg per day.

Anxiety

- The usual recommended starting dose is one 80mg capsule daily.
- If necessary, the dose may be increased to one 160mg capsule daily.
- You should be reviewed after 6 to 12 months' treatment.

High blood pressure in the belly region and lower throat (portal hypertension)

- The usual recommended starting dose is one 80mg capsule daily.
- If necessary, the dose can be increased in 80mg increments up to a maximum of 320mg per day.

Older people

- The usual recommended starting dose is one 80mg capsule daily.
- If necessary, the dose may be increased to one 160mg capsule daily.

Use in children

Propranolol should not be given to children.

If you take more Propranolol than you should

If you accidentally take too many capsules, contact your doctor or nearest hospital emergency department **immediately** for advice. Remember to take this leaflet or any remaining capsules with you,

Symptoms of overdose may include: slower heartbeat (bradycardia), low blood pressure (hypotension), heart problems and difficulty in breathing or wheezing (bronchospasm)

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

Take it as soon as you remember, unless it is nearly time for your next dose. If you miss a dose, **do not** take a double dose to make up for a forgotten dose.

If you stop taking Propranolol

It is important that you keep taking this medicine for as long as your doctor has told you to. Your doctor will gradually reduce your dose over a period of 7 – 14 days before you stop taking this medicine.

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.

Seek medical advice immediately if you develop the following symptoms:

- Allergic reactions: swelling of the face, throat or tongue, difficulty breathing or dizziness
- Difficulty in breathing. This is more likely if you have asthma or a history of asthmatic problems

Common side effects (may affect up to 1 in 10 people)

- Cold hands and feet
- Weakness

- Tiredness (fatigue)
- Difficulty in sleeping (insomnia)
- Nightmares
- Slow heartbeat (bradycardia)
- Poor blood circulation which makes the toes and fingers numb and pale (Raynaud's syndrome)

Uncommon side effects (may affect up to 1 in 100 people)

- Feeling sick (nausea)
- Being sick (vomiting)
- Diarrhoea

Rare side effects (may affect up to 1 in 1,000 people)

- Light-headedness, fainting or dizziness especially when going from sitting or lying position to standing up (postural hypotension)
- Worsening of pain and/or cramping in the lower leg (intermittent claudication)
- Worsening of heart failure, which can cause shortness of breath or ankle swelling
- Tingling or numbness in the hands or feet (paraesthesia)
- Confusion
- Dizziness
- Skin rash
- Dry eyes
- Visual disturbances
- Seeing or hearing things that are not real (hallucinations or psychosis)
- Mood changes
- Memory loss
- Worsening of a common skin condition known as psoriasis
- Hair loss (alopecia)
- Reduction in blood platelets, which increases the risk of bleeding or bruising (thrombocytopaenia)
- Skin rash resulting from bleeding into the skin (purpura)

Very rare side effects (may affect less than 1 in 10,000 people)

- Increase in ANA (Anti-Nuclear Antibodies – detected through blood test)
- Severe muscle weakness or worsening of the condition (myasthenia gravis)

Other side effects (frequency not known)

- Headaches
- Inability to achieve or maintain an erection (impotence)
- Low levels of sugar in the blood (hypoglycaemia). This can happen in people with or without diabetes. This includes newborns, infants, children, older people, people on artificial kidneys (haemodialysis) or people taking medicines for diabetes. It may also happen if you are fasting or suffer with long-term liver disease

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 this medicine

- Keep this medicine out of the sight and reach of children.
- Store below 25°C.
- Store in the original package in order to protect from light and moisture.
- Do not use this medicine after the expiry date which is stated on the carton/blister/container after EXP. 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 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 Capsules contain:

- Each 160mg sustained release capsule contains 160mg of propranolol hydrochloride.
- Each 80mg sustained release capsule contains 80mg of propranolol hydrochloride

The other ingredients are: neutral microgranules, povidone, ethylcellulose, talc, gelatine, titanium dioxide (E171) and sulfur dioxide (E220).

What Propranolol Capsules look like and the contents of the pack:

- Propranolol 160mg are white, hard gelatine, size 2, sustained release capsules, filled with white microgranules.
- Propranolol 80mg are opaque white caps with colourless transparent bodies, size 3, sustained release gelatine capsules filled with regular creamy white microgranules.

Propranolol Capsules are available in:

- Propranolol 160mg Capsules are available in packs of 28 and 100 capsules
- Propranolol 80mg Capsules are available in packs of 28 capsules.

Not all pack sizes or pack types may be marketed.

Product Licence Numbers:

- Propranolol 160mg SR Capsules – PL 11311/0001
- Propranolol 80mg SR Capsules – PL 11311/0017

Marketing Authorisation Holder and Manufacturer:

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