APO-Propranolol Tablets

Propranolol hydrochloride

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about propranolol. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may want to read it again.

What this medicine is used for

Propranolol is used to treat or prevent a number of conditions, most of which are related to the heart:

- to lower high blood pressure, also called hypertension
- · to prevent angina
- to treat or prevent heart attacks, or reduce your risk of heart problems following a heart attack
- to treat irregularities in heartbeat, including those caused by anxiety
- essential tremor (shaking of head, chin, hands)
- · phaeochromocytoma
- Fallot's Tetralogy
- to prevent migraine headaches

Propranolol belongs to a group of medicines called beta-blockers.

How it works

Propranolol works by affecting the body's response to some nerve impulses, especially in the heart. This decreases the heart's need for blood and oxygen, which reduces the amount of work the heart must do. Propranolol also widens the blood vessels in the body and helps the heart to beat more regularly.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed this medicine for another reason.

This medicine is available only with a doctor's prescription.

This medicine is not addictive.

There is not enough information to recommend the use of this medicine in children under 7 years of age.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- propranolol hydrochloride
- any of the ingredients listed at the end of this leaflet.
- Any other similar medicines such as beta-blockers

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing

- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin.
- Fast heart beats (palpitations)
- Extreme tiredness or breathlessness and mild exercise

Do not take this medicine if you have or have had any of the following medical conditions:

- heart failure or an enlarged heart
- problems with heart rhythm or a slow heartbeat
- second and third degree atrioventricular block
- low blood pressure (also known as hypotension)
- blood circulation problems
- · Prinzmetal's angina
- asthma or severe breathing problems
- low blood sugar levels

Taking propranolol may make these conditions worse.

Do not take this medicine if you are pregnant or plan to become pregnant or are breastfeeding.

Propranolol may affect your developing baby if you take it during pregnancy. It may also pass into breast milk. Your doctor can discuss with you the risks involved.

Do not take this medicine after the expiry date printed on the pack or the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- asthma or serious breathing problems
- heart problems
- low blood pressure
- problems with your circulation
- · diabetes or low blood sugar
- · an overactive thyroid gland
- · liver problems
- · kidney problems

Tell your doctor if you are fasting or have been fasting recently.

Propranolol may cover up some of the symptoms of low blood sugar, such as an increased heart rate.

Tell your doctor if you are planning to have surgery, dental treatment or an anaesthetic.

When combined with anaesthetics, propranolol may cause a sudden drop in blood pressure.

If you have not told your doctor about any of the above, tell them before you start taking propranolol.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and propranolol may interfere with each other. These include:

- calcium channel blockers and beta blockers, medicines used to treat heart conditions
- medicines used for heart rhythm problems (e.g. lignocaine, disopyramide, amiodarone, flecainide)
- digoxin, a medicine used to treat heart failure
- clonidine, a medicine used to treat high blood pressure

- medicines used to treat migraine (e.g. rizatriptan)
- medicines for diabetes
- warfarin, a medicine that stops blood clots
- theophylline, a medicine used to treat asthma
- rifampicin, a medicine used to treat tuberculosis
- ibuprofen and indomethacin, medicines used to treat pain and inflammation
- cimetidine, a medicine used to treat ulcers
- chlorpromazine, a medicine used to treat psychotic illnesses

These medicines may affect the way propranolol works or may be affected by propranolol. You may need to use different amounts of your medicines or take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking propranolol.

Other medicines not listed above may also interact with this medicine.

How to take this medicine

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

If you are taking other medicines which lower blood pressure, your doctor may need change the dose of them to obtain the best results for you.

For high blood pressure

The usual starting dose is one 40 mg tablet taken twice a day.

After one week, the dose may be increased to between 120 mg to 320 mg daily.

For angina and tremor

The usual starting dose is one 40 mg tablet taken two to three times a day.

To treat or prevent heart attack

The usual dose is 80 mg taken twice a day, often starting with one 40 mg tablet taken four times a day for 2 or 3 days.

For migraine prevention

Adults

The usual dose is one 40 mg tablet taken twice a day. This may need to be increased up to 80 mg twice a day.

Children over 7 years

The starting dose is one 10 mg tablet taken once or twice daily. This can be increased if necessary.

How to take it

Swallow the tablet whole with a full glass of water.

When to take it

Take this medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take propranolol with or without food.

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time to take your next dose (within 6 hours), skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for missed doses.

This may increase the chance of you experiencing side effects.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention. Propranolol is severely toxic if you take too much.

Signs of an overdose may include difficulty in breathing, light headedness or dizziness, feeling very tired, fits, slow heart beat or coma.

While you are taking this medicine

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking propranolol.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

If you have a severe allergic reaction to foods, medicines, or insect stings, tell your doctor immediately.

If you have a history of allergies, there is a chance that propranolol may cause allergic reactions to be worse and harder to treat.

If you become pregnant whilst taking propranolol, tell your doctor immediately.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

You may feel light-headed or dizzy when you begin to take propranolol.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem gets worse or continues, talk to your doctor.

If you are going to have surgery, tell the surgeon and anaesthetist that you are taking propranolol.

Your blood pressure may drop suddenly due to propranolol interacting with the anaesthetic.

If you are being treated for diabetes, make sure you check your blood sugar level regularly and report any changes to your doctor.

Propranolol may change how well your diabetes is controlled. It may also cover up some of the symptoms of low blood sugar (hypoglycaemia) such as an increased heart rate. It may also increase the time your body takes to recover from low blood sugar. Your doses of diabetic medicines, including insulin, may need to change.

Propranolol may also occasionally cause low blood sugar (hypoglycaemia) in non-diabetic patients.

This may include newborn infants, toddlers, children, elderly, patients suffering from overdose, patients suffering from chronic liver disease, fasting patients or patients on haemodialysis.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.

Things you must not do

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not take your medicine to treat any other complaints unless your doctor tells you to.

Do not stop taking your medicine or change the dosage without first checking with your doctor.

Your doctor may want you to gradually reduce the amount of propranolol you are taking before stopping completely. This may help reduce the possibility of your condition getting worse.

Things to be careful of

Be careful driving or operating machinery until you know how this medicine affects you.

Propranolol may cause dizziness, light-headedness, tiredness, or drowsiness in some people. Make sure you know how you react to this medicine before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed.

Be careful when drinking alcohol while you are taking propranolol.

Dizziness or light-headedness may be worse. Alcohol can also increase the effects of propranolol.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem gets worse or continues, talk to your doctor.

Dress warmly during cold weather, especially if you will be outside for a long time (for example when playing winter sports).

Propranolol, like other beta-blocker medicines, may make you more sensitive to cold temperatures, especially if you have circulation problems.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking propranolol.

Propranolol helps most people but may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- nausea (feeling sick) or vomiting
- · loss of appetite
- diarrhoea, stomach pain, flatulence
- · cold hands or feet
- · dizziness, tiredness
- · rash, flushing
- hair loss
- feeling tired, lethargic, lack of energy

The above list contains the more common side effects of propranolol.

Tell your doctor as soon as possible if you notice any of the following.

- disturbed sleep, vivid dreams or nightmares
- conjunctivitis, dry eyes, visual disturbances
- · trouble passing urine
- · unexplained bruising
- · mood changes, confusion
- sexual problems
- loss of hearing
- slow heart beats

The above list includes serious side effects that may require medical attention.

If any of the following happen, stop taking your medicine and contact your doctor immediately or go to Accident and Emergency at your nearest hospital:

- extreme tiredness or breathlessness on mild exercise
- wheezing, difficulty breathing or an asthma attack
- fast heart beats (palpitations)
- shortness of breath, wheezing or difficulty breathing; swelling of

the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin (signs of an allergic reaction)

The above list contains very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may occur in some patients.

Storage and disposal

Storage

Keep the tablets in the bottle until it is time to take them.

If you take the tablets out of the bottle they may not keep well.

Keep your medicine away from direct sunlight and in a cool dry place, where the temperature stays below 25°C.

Do not store your medicine or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-anda-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

10 mg tablet

Orange coloured, round, biconvex tablets, embossed with "P" and "10" on either side of the breakline on one side and plain on the other side.

Bottles of 100 tablets.

AUST R 222958.

40 mg tablet

Green coloured, round, biconvex tablets, embossed with "P" and "40" on either side of the breakline on one side and plain on the other side.

Bottles of 100 tablets. AUST R 222969.

* Not all strengths may be available.

Ingredients

Each tablet contains 10 mg or 40 mg propranolol hydrochloride as the active ingredient.

It also contains the following:

- · lactose monohydrate
- maize starch
- sunset yellow FCF aluminium lake
- · quinoline yellow
- povidone
- · sodium starch glycollate
- · magnesium stearate
- brilliant blue FCF aluminium lake (40 mg only)

This medicine does not contain gluten, sucrose, tartrazine and other azo dyes.

Sponsor

Arrotex Pharmaceuticals Pty Ltd 15 – 17 Chapel Street Cremorne VIC 3121 www.arrotex.com.au

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