

APO-Propranolol Tablets

Contains the active ingredient propranolol hydrochloride

Consumer Medicine Information

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

What is in this leaflet

Read this leaflet carefully before taking your medicine.

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

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up-to-date leaflet from www.apotex.com.au.

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.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine APO-Propranolol tablets. It contains the active ingredient propranolol hydrochloride.

It 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

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.

How it works

Propranolol hydrochloride is a Beta-adrenoreceptor blocking agent which acts non selectively on Beta-receptors (Beta1 and Beta 2). Propranolol hydrochloride reduces elevated blood pressure by an unknown mechanism.

There is no evidence that this medicine is addictive.

Use in children

This medicine should not be used 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 or have had any of the following:**
 - Congestive heart failure
 - Right ventricular failure secondary to pulmonary hypertension
 - Significant right ventricular hypertrophy
 - Sick sinus syndrome
 - Sinus bradycardia (less than 45 to 50 beats/minute)
 - Second and third degree A-V block
 - Hypotension
 - Severe peripheral arterial circulatory disturbances
 - Prinzmetal's angina
 - Any other similar medicines such as beta blockers
 - You have asthma or severe breathing problems
 - Other heart problems for example heart failure, low blood pressure, problems with your circulation, or a slow heartbeat.
- **You have low blood sugar levels.**
- **You are pregnant.**
Propranolol hydrochloride may affect your developing baby if you take it during pregnancy.
- **You are breastfeeding.**
Propranolol hydrochloride may pass into human breast milk.
- **You are hypersensitive to, or have had an allergic reaction to, propranolol hydrochloride or any of the ingredients listed at the end of this leaflet.**
Symptoms of an allergic reaction may include: cough, 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; fainting; or hay fever-like symptoms.
If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.
- **The expiry date (EXP) printed on the pack has passed.**
- **The packaging is torn, shows signs of tampering or it does not look quite right.**

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - 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
3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
 4. You are currently breastfeeding or you plan to breastfeed. Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.
 5. You are planning to have surgery or an anaesthetic.
 6. You are currently receiving or are planning to receive dental treatment.
 7. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with propranolol hydrochloride. These include:

- calcium channel blockers - medicines used to treat high blood pressure
- digoxin - a medicine used to treat heart failure
- medicines for migraine
- 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, indomethacin - medicines used to treat pain and inflammation
- cimetidine - a medicine used to treat ulcers
- chlorpromazine - a medicine used to treat psychotic illnesses
- rizatriptan - a medicine used to treat migraine headaches

If you are taking any of these you may need a different dose or you may need to take different medicines.

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

How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

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.

For high blood pressure

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

The dose is then usually increased to between 120 mg to 320 mg daily.

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

For angina and tremor

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

For migraine prevention

Adults

The usual dose is 40 mg 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 10 mg taken once or twice daily. This can be increased if necessary.

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

How to take it

Take tablet with a glass of water.

When to take it

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

It does not matter if you take it before, with or after 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, skip the missed dose and take your next dose at the usual time. 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 have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breastfeed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital. Your blood pressure may drop suddenly if propranolol hydrochloride interacts with the anaesthetic

- you are being treated for diabetes, make sure you check your blood sugar level regularly and report any changes to your doctor. Propranolol hydrochloride may change how well your diabetes is controlled. It may also cover up some of the symptoms of low blood sugar (hypoglycaemia) e.g. 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.

Non-diabetic patients:

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

These may include the newly born, toddlers, children, elderly, patients suffering from overdose, patients suffering from chronic liver disease, fasting patients or patients on haemodialysis.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

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

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

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

Propranolol hydrochloride 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 drinking alcohol while you are taking propranolol hydrochloride.

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

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

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

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking propranolol hydrochloride or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

- Nausea (feeling sick), vomiting
- Loss of appetite
- Diarrhoea, stomach pain, flatulence
- Cold hands or feet

- Dizziness, tiredness
- Rash, flushing
- Hair loss
- Feeling tired, lethargic, lack of energy

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

These may be serious side effects and you may need medical attention:

- 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

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects and you may need urgent medical attention or hospitalisation:

- Extreme tiredness or breathlessness on mild exercise
- Wheezing, difficulty breathing or an asthma attack
- Fast heart beats (palpitations)

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

Allergic reactions

If you think you are having an allergic reaction to propranolol hydrochloride, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, 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
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine away from direct sunlight and in a cool dry place, where the temperature will stay 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 this medicine where children cannot reach it.

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

Disposal

If your doctor tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Propranolol tablets 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.
- **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.

* 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 inactive ingredients:

- lactose
- 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 is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

- APO-Propranolol 10 mg tablets (bottle):
AUST R 222958.
- APO-Propranolol 40 mg tablets (bottle):
AUST R 222969.

Sponsor

Apotex Pty Ltd

16 Giffnock Avenue
Macquarie Park NSW 2113

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