

Apo-Propranolol

Propranolol hydrochloride

10mg and 40mg Tablets

What is in this leaflet

Please read this leaflet carefully before you start using Apo-Propranolol.

This leaflet answers some common questions about Apo-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 Apo-Propranolol against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine. You may need to read it again.

What Apo-Propranolol is used for

The name of your medicine is Apo-Propranolol tablet. It contains the active ingredient Propranolol hydrochloride.

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

- Management of angina pectoris.
- Long term prophylaxis after recovery from acute myocardial infarction.
- Control of most forms of cardiac dysrhythmias.
- Control of essential and renal hypotension
- Prophylaxis of migraine.
- Control of anxiety and anxiety tachycardia
- Management of essential tremor.
- Adjunctive management of thyrotoxicosis and thyrotoxic crisis.
- Management of hypertrophic obstructive cardiomyopathy.
- Management of phaeochromocytoma (with an alpha-adrenoreceptor blocking medicine).

Your doctor may have prescribed Apo-Propranolol for another reason.

Ask your doctor if you have any questions about why Apo-Propranolol has been prescribed for you.

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

There is no evidence that this medicine is addictive.

Apo-Propranolol dose should not be individually determined when administered to children.

Before you use Apo-Propranolol

When you must not use it

Do not use Apo-Propranolol if:

- **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, difficulty breathing or tightness in chest; 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.

- **Propranolol must not be used if there is a history of bronchospasm or bronchial asthma.**
- **Propranolol as with other beta-adrenoreceptor blocking medicines must not be used in patients with and of the following:**
 - known hypersensitivity to the substance
 - second or third degree heart block
 - cardiogenic shock
 - uncontrolled heart failure
 - hypotension
 - severe peripheral arterial circulatory disturbances
 - untreated phaeochromocytoma
 - Prinzmetal's angina
 - bradycardia
 - sick sinus syndrome
 - metabolic acidosis
 - after prolonged fasting
- **The expiry date (EXP) printed on the pack has passed.**

If you take it after the expiry date has passed, it may have no effect at all, or worse, there may be an entirely unexpected effect.

- **The packaging is torn, shows signs of tampering or it does not look quite right.**

If you are not sure whether you should start using Apo-Propranolol, talk to your doctor.

Before you start to use it

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:

- A history of cardiac failure
- problems with your circulation
- heart problems
- low blood pressure
- diabetes or low blood sugar
- an overactive thyroid gland or thyrotoxicosis
- slow heart rate
- asthma or serious breathing problems
- liver problems including cirrhosis
- 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 breast-feed.

Do not take this medicine whilst breastfeeding.

Propranolol can pass into breast milk and may affect your baby. Breast-feeding is therefore not recommended.

5. You are planning to have surgery or an anaesthetic.

6. You are currently receiving or are planning to receive dental treatment.

If you have not told your doctor about any of the above, tell them before you start using Apo-Propranolol.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking Apo-Propranolol.

Some medicines may interfere with Apo-Propranolol. These include:

- calcium channel blockers - medicines used to treat high blood pressure
- sodium channel blockers – medicine used to treat tachycardia
- adrenaline
- 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
- thioridazine – a medicine used to treat schizophrenia and psychosis
- lignocaine – a medicine used to numb tissue in a specific area
- anaesthesia agents – medicines used to enable painless medical procedures to be performed

These medicines may be affected by Apo-Propranolol, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Other medicines not listed above may also interact with propranolol.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Apo-Propranolol.

How to use Apo-Propranolol.

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

The label should be carefully read

How much to take

Hypertension:

A starting dose of 80mg twice a day may be increased at weekly intervals according to response. The usual dose range is 160-320mg per day. With concurrent diuretic or other anti-hypertensive drugs a further reduction of blood pressure is obtained.

Angina, Anxiety, Migraine and Essential Tremor:

A starting dose of 40mg two or three times daily may be increased by the same amount at weekly intervals according to patient response. An adequate response in anxiety, migraine and essential tremor is usually seen in the range 80-160mg/day and in angina in the range 120-240mg/day.

Dysrhythmias, Anxiety Tachycardia, Hypertrophic Obstructive Cardiomyopathy and Thyrotoxicosis:

A dosage range of 10-40mg three to four times a day usually achieves the required response.

Post Myocardial Infarction:

Treatment should start 5-21 days after myocardial infarction, with an initial dose of 40mg four times a day for 2-3 days. In order to improve compliance the total daily dose can thereafter be given as 80mg twice a day.

Phaeochromocytoma:

To be used only with an alpha-adrenoreceptor blocking medicine.

Pre-operative:

60mg daily for 3 days is recommended.

Non-operative malignant cases:

30mg daily.

Elderly:

Evidence concerning the relationship between the blood levels and age is conflicting. With regard to the elderly, the optimum dose should be individually determined according to clinical response.

Paediatric population

The dose should always be individually determined. The following doses are intended only as a guide.

Dysrhythmias, Phaeochromocytoma and Thyrotoxicosis:

0.25-0.5mg/kg three or four times daily as required.

Migraine:

Under age of 12: 20mg two or three times daily.

Over age of 12: The adult dose.

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.

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

How to take it

Swallow the tablet(s) 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.

How long to take it

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

Your doctor will advise you when you can stop taking Apo-Propranolol completely.

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.

While you are using Apo-Propranolol

Things you must do

Immediately stop taking Apo-Propranolol and check with your doctor if a skin rash or other allergic reaction occurs.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking Apo-Propranolol.

Take your medicine exactly as your doctor has prescribed.

Tell all doctors, dentists and pharmacists who are treating you that you are taking this medicine.

Tell your doctor (immediately) if you become pregnant while you are taking it.

Visit your doctor regularly. Your doctor needs to check your progress and see whether you need to keep taking Apo-Propranolol.

Always discuss with your doctor any problems or difficulties during or after taking Apo-Propranolol.

Tell your doctor if for any reason, you have not taken your medicine exactly as prescribed. Otherwise your doctor may think that it was not effective and change your treatment unnecessarily.

Keep enough Apo-Propranolol to last weekends and holidays.

Things you must not do

Do not give Apo-Propranolol to anyone else, even if they have the same condition as you.

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

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

Do not take any other medicine while you are taking Apo-Propranolol without first telling your doctor.

Do not take Apo-Propranolol for a longer time than your doctor has prescribed.

Things to be careful of

Do not drive, operate machinery, or participate in any dangerous activities where alertness is required, until you know how Apo-Propranolol affects you.

Dizziness or fatigue may occasionally occur during treatment with propranolol, patients driving vehicles or operating machinery should exercise caution until they have determined their reaction to the drug.

Caution must be exercised when using anaesthetic agents with propranolol. It may be decided to discontinue therapy with this medicine before surgery, in which case a gradual withdrawal is recommended. If it is decided not to discontinue therapy before surgery, care should be taken when using anaesthetic agents with propranolol. The anaesthetist should be informed so the choice of anaesthetic agent can be decided. Anaesthetic agents causing myocardial depression are best avoided.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Apo-Propranolol.

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

If you take too much propranolol, it may cause bradycardia, hypotension, bronchospasm or acute cardiac failure.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Apo-Propranolol or if you have any questions or concerns.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

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

Propranolol is generally well tolerated.

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

This list includes the most common side effects. Mostly, these are mild and transient:

- Nausea (feeling sick), vomiting
- Diarrhoea, stomach pain, flatulence
- Loss of appetite (including anorexia)
- Cold hands or feet
- Dizziness, tiredness
- Rash, flushing
- Hair loss
- Feeling tired, lethargic, lack of energy

Tell your doctor immediately if you notice any of the following.

These may be serious side effects. 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 or someone you know or care for experience any of the following, stop taking propranolol and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

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

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

After using Apo-Propranolol

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 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.

No special requirements for disposal.

Any unused medicine or waste material should be disposed of in accordance with local requirements.

Product description

What it looks like

Apo-Propranolol 10mg tablets: 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.

Apo-Propranolol 40mg tablets: 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.

The score line is not intended for breaking the tablet.

Apo-Propranolol 10mg and 40mg tablets are available in bottles of 100 tablets.

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Active ingredient:

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

Inactive ingredients:

- Lactose monohydrate
- Corn starch
- Sodium starch glycollate
- Magnesium stearate
- Povidone

The 10mg tablets also contain the colourants:

- Sunset Yellow (CI15985)
- Quinoline Yellow (CI47005)

The 40mg tablets also contain the colourants:

- Sunset Yellow (CI15985),
- Quinoline Yellow (CI47005)
- Brilliant Blue (CI42090)

This medicine is gluten free.

This medicine contains lactose.

Sponsor Details

Apo-Propranolol is supplied in New Zealand by:

Apotex NZ Ltd
32 Hillside Road
Glenfield
Auckland
New Zealand
Phone: (09) 64 9444 2073

Date of Preparation

This leaflet was prepared on 17 June 2019.