

APO-PROPRANOLOL

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using APO-Propranolol?

APO-PROPRANOLOL contains the active ingredient propranolol hydrochloride. APO-PROPRANOLOL is used to treat or prevent a number of conditions, most of which are related to the heart. For more information, see Section [1. Why am I using APO-Propranolol?](#) in the full CMI.

2. What should I know before I use APO-Propranolol?

Do not use if you have ever had an allergic reaction to propranolol hydrochloride or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section [2. What should I know before I use APO-Propranolol?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with APO-Propranolol and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use APO-Propranolol?

- Your doctor will tell you what dose to take.
- More instructions can be found in Section [4. How do I use APO-Propranolol?](#) in the full CMI.

5. What should I know while using APO-Propranolol?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using APO-PROPRANOLOL.If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking APO-PROPRANOLOL.Call your doctor straight away if you have a severe allergic reaction to foods, medicines or insect stings, feel light-headed, dizzy or faint, and this problem gets worse or continues, plan to have surgery (even at the dentist) that needs a general anaesthetic or become pregnant while taking APO-PROPRANOLOL.
Things you should not do	<ul style="list-style-type: none">Do not give APO-PROPRANOLOL to anyone else even if they have the same condition as you.Do not use APO-PROPRANOLOL to treat any other complaints unless your doctor tells you to.Do not stop taking APO-PROPRANOLOL without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">Be careful before you drive or use any machines or tools until you know how APO-PROPRANOLOL affects you.
Drinking alcohol	<ul style="list-style-type: none">Tell your doctor if you drink alcohol.Alcohol may increase the effects of APO-PROPRANOLOL.
Looking after your medicine	<ul style="list-style-type: none">Store below 25°C.Store in a cool, dry place away from young children.

For more information, see Section [5. What should I know while using APO-Propranolol?](#) in the full CMI.

6. Are there any side effects?

Common side effects include: nausea (feeling sick), vomiting, loss of appetite, diarrhoea, stomach pain, flatulence, cold hands or feet, dizziness, tiredness, rash, flushing, hair loss, feeling tired, lethargic or lack of energy. Serious side effects include: depression, disturbed sleep, vivid dreams or nightmares, conjunctivitis, dry eyes, visual disturbances, trouble passing urine, unexplained bruising, mood changes, confusion, sexual problems, loss of hearing or slow heart beats. Very serious side effects include: extreme tiredness or breathlessness on mild exercise, wheezing, difficulty breathing or an asthma attack or fast heart beats (palpitations).

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

APO-PROPRANOLOL

Active ingredient(s): *propranolol hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using APO-Propranolol. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using APO-Propranolol.**

Where to find information in this leaflet:

- [1. Why am I using APO-Propranolol?](#)
- [2. What should I know before I use APO-Propranolol?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use APO-Propranolol?](#)
- [5. What should I know while using APO-Propranolol?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using APO-Propranolol?

APO-PROPRANOLOL contains the active ingredient propranolol hydrochloride. APO-PROPRANOLOL belongs to a group of medicines called beta-blockers. It works by affecting the body's response to some nerve impulses, especially in the heart.

As a result, it decreases the heart's need for blood and oxygen and therefore reduces the amount of work the heart has to do. It also widens the blood vessels in the body, as well as helping the heart to beat more regularly.

APO-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

2. What should I know before I use APO-Propranolol?

Warnings

Do not use APO-Propranolol if:

- you are allergic to propranolol hydrochloride, or any of the ingredients listed at the end of this leaflet.
- you are allergic to other similar medicines such as beta
- blockers.

Always check the ingredients to make sure you can use this medicine.

- you have asthma or severe breathing problems including 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
- you have certain other heart problems for example heart failure, low blood pressure, problems with your circulation, Prinzmetal's angina, or a slow heart beat.
- you have low blood sugar levels

Taking APO-PROPRANOLOL may make these conditions worse.

Check with your doctor if you:

- have any other medical conditions, including
- asthma or serious breathing problems
- heart problems, heart failure or an enlarged heart
- problems with heart rhythm or a slow heartbeat
- second and third degree atrioventricular block
- low blood pressure (hypotension)
- problems with your circulation
- diabetes or low blood sugar
- an overactive thyroid gland
- liver problems
- kidney problems
- Prinzmetal's angina
- take any medicines for any other condition
- have allergies to any other medicines, food, preservatives or dyes.
- 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

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.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your baby can take in APO-PROPRANOLOL from breast milk if you are breastfeeding.

3. What if I am taking other medicines?

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

Some medicines may interfere with APO-PROPRANOLOL and affect how it works, and some medicines may be affected by APO-PROPRANOLOL. These medicines include:

- calcium channel blockers - medicines used to treat high blood pressure
- 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 for 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, 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.

You may need to use different amounts of your medicines, or take different medicine. Your doctor will advise you.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect APO-Propranolol.

4. How do I use APO-Propranolol?

How much to take

- 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 40 mg taken two or three times a day.
- To treat or prevent heart attack
 - 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.
- Other conditions
 - Your doctor will tell you what dose to take.
 - Follow the instructions provided and use APO-PROPRANOLOL until your doctor tells you to stop.

When to take APO-Propranolol

- APO-PROPRANOLOL should be used regularly at the same time each day.
- If you forget to use APO-PROPRANOLOL
- **If it is almost time for 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 tablets as you would normally. Do not take a double dose to make up for the dose you missed.

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

How long to take APO-Propranolol

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 use too much APO-PROPRANOLOL

If you think that you have used too much APO-PROPRANOLOL, you may need urgent medical attention. APO-PROPRANOLOL is severely toxic if you take too much. Taking too much causes difficulty in breathing, light-headedness or dizziness, feeling very tired, fits, slowed heartbeat or coma.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

If you forget to use APO-Propranolol

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.

5. What should I know while using APO-Propranolol?

Things you should do

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

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

Call your doctor straight away if you:

- Have a severe allergic reaction to foods, medicines or insect stings
 - If you have a history of allergies, there is a chance that APO-PROPRANOLOL may cause allergic reactions to be worse and harder to treat.
- feel light-headed, dizzy or faint, and this problem gets worse or continues
 - get up slowly when getting out of bed or standing up
 - You may feel light-headed or dizzy when you begin to take APO-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.
- plan to have surgery (even at the dentist) that needs a general anaesthetic
 - Your blood pressure may drop suddenly if APO-PROPRANOLOL interacts with the anaesthetic.
- become pregnant while taking APO-PROPRANOLOL
- have diabetes and notice any blood sugar level changes
 - APO-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 increased heart rate.
- APO-PROPRANOLOL may increase the time your body takes to recover from low blood sugar. Your doses of diabetic medicines, including insulin, may need to change.
- do not have diabetes and notice a low blood sugar (hypoglycaemia)
 - 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.
- **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
- Remind any doctor, dentist or pharmacist you visit that you are using APO-PROPRANOLOL.

Things you should not do

- Do not give APO-PROPRANOLOL to anyone else even if they have the same condition as you.
- Do not use APO-PROPRANOLOL to treat any other complaints
- unless your doctor tells you to.
- Do not stop taking APO-PROPRANOLOL without checking with your doctor. Your doctor may want you to gradually reduce the amount of APO-PROPRANOLOL you are taking before stopping completely. This may help reduce the possibility of your condition getting worse

Driving or using machines

Be careful before you drive or use any machines or tools until you know how APO-Propranolol affects you.

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

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.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may increase the effects of APO-PROPRANOLOL. Dizziness or light-headedness may be worse.

Things to be careful of

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

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

Please talk to your doctor or pharmacist about these possibilities if you think they may bother you.

Looking after your medicine

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

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place where the temperature stays below 25°C, away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Gut-related:</p> <ul style="list-style-type: none"> • nausea (feeling sick) • vomiting • loss of appetite • diarrhoea, stomach pain, flatulence <p>Other:</p> <ul style="list-style-type: none"> • cold hands or feet • dizziness, tiredness • rash, flushing • hair loss • feeling tired, lethargic, lack of energy 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Head-related:</p> <ul style="list-style-type: none"> • depression • disturbed sleep, vivid dreams or nightmares • visual disturbances • mood changes, confusion • loss of hearing <p>Other:</p> <ul style="list-style-type: none"> • unexplained bruising • sexual problems • slow heart beats • conjunctivitis, dry eyes • visual disturbances • trouble passing urine 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Very Serious side effects

Very serious side effects	What to do
<p>Allergic reaction-related:</p> <ul style="list-style-type: none"> • 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) 	<p>Stop taking this medicine and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

Who distributes APO-Propranolol:

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

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7. Product details

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

What APO-Propranolol contains

Active ingredient (main ingredient)	Each tablet contains 10 mg or 40 mg propranolol hydrochloride as the active ingredient.
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• 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)
Potential allergens	This medicine does not contain gluten, sucrose, tartrazine and other azo dyes.

Do not take this medicine if you are allergic to any of these ingredients.

What APO-Propranolol 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. APO- PROPRANOLOL TABLETS 5.

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.