

Consumer Medicine Information (CMI) summary

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

1. Why am I taking PRESOLOL?

PRESOLOL contains the active ingredient labetalol hydrochloride. PRESOLOL is used to lower high blood pressure, also called hypertension.

For more information, see Section [1. Why am I taking PRESOLOL?](#) in the full CMI.

2. What should I know before I take PRESOLOL?

Do not use if you have ever had an allergic reaction to labetalol 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 take PRESOLOL?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with PRESOLOL 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 take PRESOLOL?

- Swallow the tablets whole with a glass of water.
- Take your medicine immediately after meals.

More instructions can be found in Section [4. How do I take PRESOLOL?](#) in the full CMI.

5. What should I know while taking PRESOLOL?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are taking PRESOLOL. If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. • If you become pregnant while taking this medicine, tell your doctor immediately.
Things you should not do	• Do not take PRESOLOL to treat any other complaints unless your doctor tells you to. • Do not give your medicine to anyone else, even if they have the same condition as you. • Do not stop taking your medicine or change the dosage without checking with your doctor.
Driving or using machines	• Be careful driving or operating machinery until you know how PRESOLOL affects you.
Drinking alcohol	• Tell your doctor if you drink alcohol. Alcohol may worsen symptoms such as dizziness or light-headedness.
Looking after your medicine	• Keep your tablets in the original pack until it is time to take them. • Keep your tablets in a cool dry place where the temperature stays below 25°C. • Do not store PRESOLOL or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

For more information, see Section [5. What should I know while taking PRESOLOL?](#) in the full CMI.

6. Are there any side effects?

Less serious side effects include dizziness or lightheadedness, especially when getting up quickly; tiredness; lack of energy; headache; trembling; muscle cramps; unusual movements, including tremors. Serious side effects include chest tightness, wheezing, shortness of breath, swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing.

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.

PRESOLOL™

Active ingredient(s): *labetalol hydrochloride*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I taking PRESOLOL?

PRESOLOL contains the active ingredient labetalol hydrochloride. PRESOLOL belongs to a group of medicines called beta-blockers. These medicines work by changing the body's response to some nerve impulses. As a result, it widens blood vessels in the body causing blood pressure to fall.

PRESOLOL is used to lower high blood pressure, also called hypertension. Everyone has blood pressure. This pressure helps to circulate your blood all around your body. Your blood pressure may be different during different times of the day, depending on how busy or worried you are. You have hypertension (high blood pressure) when your blood pressure stays higher than normal, even when you are calm and relaxed.

There are usually no symptoms of hypertension. The only way of knowing that you have hypertension is to have your blood pressure checked on a regular basis. You may feel fine and have no symptoms, but if high blood pressure is not treated it can lead to serious health problems.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed PRESOLOL for another reason.

There is no evidence that PRESOLOL is addictive.

2. What should I know before I take PRESOLOL?

Warnings

Do not take PRESOLOL if:

- you are allergic to labetalol hydrochloride, any other beta-blocker medicines, or any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include:
 - shortness of breath
 - wheezing or difficulty breathing

- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin
- Always check the ingredients to make sure you can use this medicine.
- you have:
 - asthma, wheezing, difficulty breathing or other lung problems, or if you have had them in the past
 - a history of allergic problems, including hayfever
 - a very slow heartbeat, less than 45-50 beats per minute
 - certain other heart conditions
- after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- are not sure whether you should start taking this medicine
- have allergies to any other medicines, foods, dyes or preservatives
- have or have had any of the following medical conditions:
 - diabetes
 - breathing problems such as asthma
 - kidney problems
 - liver problems such as jaundice
 - an overactive thyroid
 - any blood vessel disorders causing poor circulation in the arms and legs
 - phaeochromocytoma, a rare tumour of the adrenal gland
 - certain types of angina, such as Prinzmetal angina or variant angina
 - shock or severe low blood pressure
 - heart failure any other heart problems

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.

PRESOLOL is not recommended for use during the first trimester of pregnancy as it may affect your developing baby.

If it is necessary for you to take PRESOLOL later in pregnancy, your doctor will discuss with you the risks and benefits involved.

Do not breast-feed if you are taking this medicine.

The active ingredient in PRESOLOL passes into breast milk and there is a possibility that your baby may be affected.

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 PRESOLOL and affect how it works.

- other beta-blocker medicines, including beta-blocker containing eye drops
- calcium channel blockers, medicines used to treat high blood pressure and angina, such as verapamil, diltiazem
- certain medicines used to treat an irregular heartbeat, such as disopyramide, quinidine
- other blood pressure medication, such as clonidine, methyldopa
- fluid tablets, also called diuretics
- cimetidine, a medicine commonly used to treat stomach ulcers
- some medicines used to treat depression
- insulin and other medicines used to treat diabetes
- guanethidine, a medicine used to treat certain heart conditions
- some medicines used during surgery and emergency situations such as anaesthetics
- non-steroidal anti-inflammatory drugs (NSAIDs), a group of medicines used to treat arthritis, pain or inflammation, such as ibuprofen, indometacin, aspirin

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

4. How do I take PRESOLOL?

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet.

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

How much to take

- The dose of PRESOLOL varies from patient to patient.
- The usual adult starting dose is 100 mg to 200 mg twice daily.
- Your doctor may change this dose depending on how you respond to this medicine. Your doctor will decide the right dose for you.
- Elderly patients may need lower doses.
- This medicine is not recommended for use in children.

When to take PRESOLOL

- **Take your medicine immediately after meals.**
- Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How to take PRESOLOL

Swallow the tablets whole with a glass of water.

How long to take it

Continue taking your medicine for as long as your doctor tells you. This medicine helps to control your condition but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take PRESOLOL

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take the missed dose 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 the dose you missed.

This may increase the chance of you getting an unwanted side effect.

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

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

If you take too much PRESOLOL

If you think that you have taken too much PRESOLOL, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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 have taken too much PRESOLOL, you may feel nausea, vomiting, dizziness, lightheaded, faintness and a very slow heart beat.

5. What should I know while taking PRESOLOL?

Things you should do

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

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

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 PRESOLOL may make allergic reactions worse and harder

to treat. **Immediately stop taking this medicine if a skin rash or any other allergic reaction occurs.**

If you are being treated for diabetes, make sure you check your blood sugar level regularly. PRESOLOL may affect how well your diabetes is controlled. It may also hide some of the symptoms of low blood sugar (also called hypoglycaemia) such as a fast heart beat. PRESOLOL may also make low blood sugar last longer. Your doctor may need to change your dose of diabetic medicines, including insulin.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

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

Things you should not do

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

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

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

Stopping PRESOLOL suddenly may cause unwanted heart problems. Your doctor may want you to gradually reduce the amount of Presolol you are taking before stopping completely. This may help reduce the possibility of heart complications from occurring.

Things to be careful of

If you feel lightheaded, 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 continues, or gets worse, talk to your doctor

Make sure you drink enough water in hot weather and during exercise when you are taking this medicine, especially if you sweat a lot.

If you do not drink enough water while taking PRESOLOL, you may feel faint, lightheaded or sick (nauseous). This is because your blood pressure is dropping suddenly.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how PRESOLOL affects you.

PRESOLOL may cause drowsiness, dizziness or lightheadedness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol. Alcohol may worsen symptoms such as dizziness or light-headedness.

Looking after your medicine

- Keep your tablets in the original pack until it is time to take them.

- Keep your tablets in a cool dry place where the temperature stays below 25°C.

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

Store it in a cool dry place 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 window sills.

Keep it where young children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

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

Do not take 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
• dizziness or lightheadedness, especially when getting up quickly • tiredness, lack of energy • headache • trembling, muscle cramps • unusual movements, including tremors • depressed mood • tingling of the skin, especially the scalp • dry, red or sore eyes, blurred vision • nausea, vomiting, upset stomach • fever or chills • increased sweating • blocked nose • problems with sexual function • swelling of the ankles	Speak to your doctor if you have any of these less serious side effects and they worry you.
• slow or irregular heartbeat • feeling generally unwell, sometimes with yellowing of the eyes or skin (jaundice) • difficulty in passing urine or unable to pass urine • any type of skin rash, redness, itching or hives	Tell your doctor as soon as possible if you notice any of these side effects.

Serious side effects

Serious side effects	What to do
• chest tightness, wheezing, shortness of breath • swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing	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.

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.

7. Product details

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

What PRESOLOL contains

Active ingredient (main ingredient)	labetalol hydrochloride
Other ingredients (inactive ingredients)	• microcrystalline cellulose • magnesium stearate • colloidal anhydrous silica • silicon dioxide • sodium starch glycollate • pregelatinised maize starch • sucrose • Opadry Orange OY-LS-23015
Potential allergens	sulfites, lactose and sugars

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

What PRESOLOL looks like

PRESOLOL 100 is 8mm normal convex orange film coated tablet marked LL 100, G on reverse (AUST R 56475).

PRESOLOL 200 is 10.5mm normal convex orange film coated tablet marked LL 200, G on reverse (AUST R 56476).

Who distributes PRESOLOL

Alphapharm Pty Ltd trading as Viatris
Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.viatris.com.au
Phone: 1800 274 276

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PRESOLOL is a Viatris company trade mark

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