

PRESOLOL

labetalol hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about PRESOLOL. 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 taking PRESOLOL against the benefits they expect it will have for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What PRESOLOL is used for

PRESOLOL contains the active ingredient labetalol hydrochloride and 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.

This medicine 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.

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 not enough information to recommend the use of this medicine in children. Safety and effectiveness have not been established in this age group.

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

There is no evidence that PRESOLOL is addictive.

Before you take PRESOLOL

When you must not take it

Do not take PRESOLOL if you have an allergy to:

- any medicine containing labetalol hydrochloride
- any of the ingredients listed at the end of this leaflet
- any other beta-blocker medicines

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

Do not take PRESOLOL if 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 heart beat, less than 45-50 beats per minute
- certain other heart conditions

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.

Do not take this medicine after the expiry date printed on the pack or if 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, dyes or preservatives.

Tell your doctor if you 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

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

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

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 PRESOLOL may interfere with each other. These include:

- 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

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

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

How to 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 bottle, 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 smaller doses.

This medicine is not recommended for use in children.

How to take it

Swallow the tablets whole with a glass of water.

When to take it

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 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 it

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 (overdose)

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

You may need urgent medical attention.

If you have taken too much PRESOLOL, you may feel nausea, vomiting, dizziness, lightheaded, faintness and a very slow heart beat.

While you are taking PRESOLOL

Things you must 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 must 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

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

This medicine 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.

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 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.

Side effects

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

This medicine helps most people with high blood pressure, but it 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 treatment if you get some of the side effects.

If you are over 65 years of age, you may have an increased chance of getting side effects.

Do not be alarmed by the following list 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:

- 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, feeling sick, vomiting, upset stomach
- fever or chills
- increased sweating
- blocked nose
- problems with sexual function
- swelling of the ankles

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

- slow or irregular heart beat
- 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.

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

- chest tightness, wheezing, shortness of breath
- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing

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

Other side effects not listed above may also occur in some people.

After taking PRESOLOL

Storage

Keep your 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 tablets in a cool dry place where the temperature stays below 30°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.

Heat and dampness can destroy some medicines.

Keep it 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 the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

PRESOLOL is available in 2 strengths of tablets:

- PRESOLOL 100 - round orange tablet marked LL 100 on one side and G on the other side
- PRESOLOL 200 - round orange tablet marked LL 200 on one side and G on the other side

Each bottle contains 100 tablets.

Ingredients

PRESOLOL contains either 100 mg or 200 mg of labetalol hydrochloride as the active ingredient

The tablets also contain the following inactive ingredients:

- microcrystalline cellulose
- magnesium stearate
- colloidal anhydrous silica
- silicon dioxide
- sodium starch glycollate
- pregelatinised maize starch
- sucrose

- Opadry Orange OY-LS-23015

PRESOLOL contains sulfites, lactose and sugars. The tablets are gluten free.

Manufacturer

PRESOLOL is made in Australia by:

Alphapharm Pty Limited

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.mylan.com.au

Australian registration numbers:

PRESOLOL 100 - AUST R 56475

PRESOLOL 200 - AUST R 56476

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