

Presolol

contains the active ingredient *labetalol hydrochloride*

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Presolol.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. 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 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 necessary, 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. Presolol helps to lower your blood pressure.

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.

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

Presolol is not recommended for use in children, as its safety and effectiveness have not been established in this age group.

Presolol 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 are allergic to medicines containing labetalol or any other beta-blocker medicine or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives, swelling of the face, lips or tongue which may cause

difficulty in swallowing or breathing, wheezing or shortness of breath.

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 Presolol 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 the risks and benefits of taking it.

Do not take Presolol if you are breastfeeding.

Presolol passes into breast milk and may affect your baby.

Do not take Presolol if the expiry date (Exp.) printed on the pack has passed.

Do not take Presolol if the packaging shows signs of tampering or the tablets do not look quite right.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you plan to become pregnant or breastfeed.

Tell your doctor if you have, or have had, any medical conditions, especially the following:

- * diabetes
- * severe kidney disease
- * 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
- * heart failure any other heart problem.

Your doctor may want to take special care if you have any of these conditions.

Tell your doctor if you plan to have surgery.

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 if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may be affected by Presolol, or may affect how well it works. These include:

- * other beta-blocker medicines, including eye drops
- * calcium channel blockers, medicines used to treat high blood pressure and angina, eg: verapamil, diltiazem
- * certain medicines used to treat an irregular heartbeat, eg: disopyramide, quinidine
- * other blood pressure medication, eg: clonidine, methyldopa
- * fluid tablets, also called diuretics
- * cimetidine, a medicine commonly used to treat stomach ulcers
- * tricyclic antidepressants, a group of 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, eg: ibuprofen, indomethacin, aspirin.

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

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

How to take Presolol

How much to take

The dose varies from patient to patient.

The usual starting dose is 100 mg to 200 mg twice daily. Your doctor may increase this dose depending on how you respond to this medicine.

Elderly patients may need smaller doses.

Follow all directions given to you by your doctor and pharmacist carefully.

How to take Presolol

Swallow the tablets with a glass of water.

When to take Presolol

It is best to take Presolol immediately after food.

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 tablets as you would normally.

Do not take a double dose to make up for the dose you missed.

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

How long to take Presolol for

To properly control your condition, Presolol must be taken every day.

Keep taking Presolol for as long as your doctor recommends.

If you take too much Presolol (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think 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 take too much Presolol, you may feel dizzy or lightheaded and you may faint. You may have a very slow heart beat.

While you are taking Presolol

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking Presolol.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Presolol.

If you become pregnant while taking Presolol, tell your doctor.

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.

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 cover up 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 plan to have surgery, including dental surgery, tell your doctor or dentist that you are taking Presolol.

If you have to have any medical tests, tell your doctor that you are taking Presolol.

Presolol may affect the results of some tests.

Visit your doctor regularly so they can check on your progress.

Things you must not do

Do not stop taking Presolol, or change the dose, 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.

Do not let yourself run out of tablets over the weekend or on holidays.

Do not use Presolol to treat any other conditions unless your doctor tells you to.

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

Things to be careful of

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

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

Be careful getting up from a sitting or lying position.

Dizziness, lightheadedness or fainting may occur, especially when you get up quickly. Getting up slowly may help.

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

If you do not drink enough water while taking Presolol, you may feel faint or lightheaded or sick. This is because your blood pressure is dropping suddenly. If you continue to feel unwell, tell your doctor.

Side effects

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

Presolol helps most people with high blood pressure, but it may have unwanted side effects in some 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 this list of possible side effects.

You may not experience any of them.

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

Tell your doctor 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
- * depressed mood
- * tingling of the skin, especially the scalp
- * dry, red or sore eyes, blurred vision
- * feeling sick, vomiting, upset stomach
- * hair loss
- * increased sweating
- * blocked nose
- * problems with sexual function
- * swelling of the ankles

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- * any type of skin rash, itching or hives
- * chest tightness, wheezing, shortness of breath
- * swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- * fast, slow or irregular heart beat
- * feeling generally unwell, sometimes with yellowing of the eyes or skin (jaundice)
- * difficulty in passing urine
- * muscle and joint pain, which may occur together with fever and skin rash
- * shortness of breath (sometimes with tiredness, weakness and reduced ability to exercise), which may occur together with swelling of the feet or legs due to fluid build up

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

After taking Presolol

Storage

Keep Presolol 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.

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 degrees C.

Do not store Presolol or any other medicine in the bathroom or near a sink.

Do not leave Presolol in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking Presolol, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Presolol comes 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 pack contains 100 tablets.

Ingredients

The active ingredient in Presolol is labetalol hydrochloride. Each Presolol tablet contains:

- * Presolol 100 - 100 mg of labetalol hydrochloride
- * Presolol 200 - 200 mg of labetalol hydrochloride.

The tablets also contain:

- * sucrose
- * lactose
- * microcrystalline cellulose
- * pregelatinised maize starch
- * sodium starch glycollate
- * silicon dioxide
- * colloidal anhydrous silica
- * magnesium stearate
- * hypromellose
- * macrogol 4000
- * titanium dioxide (E171)
- * sunset yellow FCF CI 15985 (E110).

The tablets are gluten free.

Manufacturer

Presolol is made in Australia by:
Alphapharm Pty Limited
(ABN 93 002 359 739)
Chase Building 2
Wentworth Park Road
Glebe NSW 2037
Phone: (02) 9298 3999

Medical Information
Phone: 1800 028 365

Australian registration numbers:
Presolol 100 - Aust R 56475
Presolol 200 - Aust R 56476

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