

**PACKAGE LEAFLET: INFORMATION FOR THE USER**  
**Labetalol Hydrochloride 5mg/ml Solution for Injection**

**Read all of this leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- In this leaflet Labetalol Hydrochloride 5mg/ml Solution for Injection will be called Labetalol Injection.

**In this leaflet:**

1. What Labetalol Injection is for
2. Before you are given Labetalol Injection
3. How you will be given Labetalol Injection
4. Possible side effects
5. How to store Labetalol Injection
6. Further information

**1. What Labetalol Injection is for**

Labetalol Injection belongs to a group of medicines called beta blockers.

Labetalol Injection works by causing the heart to beat more slowly and with less force. It also widens the arteries in the body. This helps to lower the pressure of the blood as it travels around the body. The result is a rapid lowering of a person's blood pressure. Labetalol Injection is given in hospital and can be used to:

- lower very high blood pressure, especially in pregnant women;
- keep your blood pressure down during an operation;
- lower high blood pressure after a heart attack.

It is very important that the doctor treats your high blood pressure, because left untreated it can cause damage to your blood vessels in the long-term. This could lead to heart attacks, kidney failure, stroke or blindness.

**2. Before you are given Labetalol Injection**

**Do not use Labetalol Injection if:**

- you are allergic to labetalol hydrochloride;
- you are allergic to any of the other ingredients of Labetalol Injection (see section 6);
- your heart cannot maintain adequate circulation of blood (cardiogenic shock);
- you have heart failure that is out of control or not responding to treatment with digitalis;
- you have a heart defect that leads to a decreased function of the heart (heart block);
- your heart has difficulty pumping the proper amount of blood to the body's tissues;
- you have a problem that is common in the elderly, related to poor control of the working of your heart (sick sinus syndrome);
- you suffer from angina (chest pains) when at rest;
- you suffer from wheezing, obstructive airways disease or asthma – taking labetalol can make your breathing worse;
- you have a tumour near your kidneys (phaeochromocytoma);
- you have increased acid levels in the blood (metabolic acidosis);
- you have a weak heart or a very slow heartbeat (less than 45 or 50 beats per minute);
- you have low blood pressure (hypotension);
- you have liver disease or your liver was affected when taking labetalol in the past;
- you have very bad circulation, especially in your hands and feet.

This medicine is not suitable for children.

If any of the above applies to you, talk to your doctor.

**Check with your doctor before you are given Labetalol Injection if:**

- you are about to receive an anaesthetic: as labetalol may mask the effects of a sudden loss of blood;
- you suffer or have suffered from any serious allergic reactions in the past;
- you have ever suffered from a skin condition called psoriasis;
- you have kidney or liver problems;
- you are receiving a procedure called MIBG scintigraphy (often used to detect certain tumours);
- you are elderly (65 years and over).
- you are scheduled for cataract surgery as Labetalol may affect your pupils during this procedure. Please tell your eye surgeon before your surgery about your treatment with this medicine. You do not need to stop treatment with this medicine unless your surgeon advises otherwise.

**Tell your doctor if you are taking any of the following medicines:**

- **Medicines used to treat your heart or blood pressure**
- (such as digitalis, clonidine, hydralazine, disopyramide, quinidine, amiodarone, calcium antagonists such as verapamil, alpha blockers such as doxazosin, diltiazem, nifedipine, ACE inhibitors, angiotensin-II antagonists, xamoterol and diuretics (water tablets).
- **Medicines to treat depression** (such as monoamine oxidase inhibitors or tricyclic antidepressants).
- **Anxiolytic and hypnotic medicines** for anxiety and sedation.
- **NSAIDs, corticosteroids** or other medicines to treat pain or inflammatory conditions.
- **Cimetidine** used to treat stomach ulcers.
- **Insulin or oral anti-diabetic drugs.**
- **Anaesthetic drugs** (such as cyclopropane, trichloroethylene, alcohol, barbiturates).
- **Phenothiazines** such as chlorpromazine.
- **Antimalarial medicines** such as halofantrine, mefloquine or quinine.
- **Medicines for stimulating the heart** e.g. adrenaline.
- **Ergot derivatives** used to treat Parkinson's disease.
- **Tropisetron** used to treat nausea.
- **Alprostadil and moxisylyte** to treat impotence.
- **Aldesleukin** for the treatment of secondary cancer of the kidney.
- **Hormones** such as oestrogen and progesterone used as contraceptives or for hormone replacement therapy.
- Any other medicine, including medicines obtained without a prescription.

Taking Labetalol Injection, at the same time as the drugs mentioned for treating your heart or blood pressure, can lead to a severe drop in blood pressure, reduced heart rate, heart failure or heart block. It is important to tell your doctor if you are taking these or any of the other drugs listed above.

The results of blood or urine tests may be affected by taking labetalol. If you need to have a blood or urine test, tell your doctor that you have been given Labetalol Injection.

**Pregnancy and breast-feeding**

Labetalol Injection should only be used during the first three months of pregnancy if it is absolutely necessary. Therefore, tell your doctor if you are pregnant or trying to become pregnant.

Labetalol Injection is not recommended whilst breast-feeding.

Nipple pain and Raynaud's phenomenon of the nipple have been reported (see section 4).

**Driving and using machines**

You may feel dizzy or tired when taking Labetalol Injection. If this happens to you, do not drive or operate machinery.

### **Important information about some of the other ingredients in Labetalol Injection**

This medicinal product contains less than 1mmol (23mg) of sodium (salt) per 20ml vial, i.e. essentially sodium (salt) free.

### **3. How you will be given Labetalol Injection**

Labetalol Injection is usually only given to patients in hospital by a doctor or anaesthetist. It may be given as an injection into a vein, or by a slow drip, depending on how quickly your blood pressure needs to be reduced.

**IMPORTANT: Your doctor will decide how the Labetalol Injection will be given to you and the correct dose for you.**

Remember: You should only be given this drug if you are lying down.

You should avoid sitting upright for three hours after being given Labetalol Injection as you may feel very dizzy and lightheaded.

While you are having Labetalol Injection your doctor may check your heart rate, blood pressure and breathing, to check your medicine is working properly.

#### **Adults:**

##### **Injection into a vein (to reduce blood pressure very quickly)**

- A dose of 50mg of Labetalol Injection will be given into your vein over a period of one minute.
- If necessary this dose can be repeated every five minutes up to three times until your blood pressure has been lowered.
- The total dose should not exceed 200mg.

##### **Slow drip into a vein (to reduce blood pressure more slowly)**

- A solution containing 1mg/ml Labetalol Injection will be made up by the doctor or nurse.
- The solution will then be given to you via a drip into your vein.
- The amount of the solution you will be given will depend on why your blood pressure needs to be lowered:
  1. To lower high blood pressure in pregnancy
    - 20mg of Labetalol Injection will be given over one hour.
    - The dose may then be doubled every 30 minutes until your blood pressure has been reduced or the dose has reached 160mg per hour.
    - Your doctor may occasionally need to use a higher dose.
  2. To lower high blood pressure after a heart attack
    - 15mg of Labetalol Injection will be given over one hour.
    - The dose may then be gradually increased up to a maximum of 120mg per hour if needed.
  3. To lower high blood pressure for other reasons
    - 2mg of Labetalol Injection will be given per minute.
    - When your blood pressure is low enough, the doctor will stop your drip.
    - Your doctor may change the rate at which the drip goes in depending on how well you are responding to the medicine.
    - The total dose given is usually between 50mg and 200mg, but occasionally higher doses may be needed.

##### **To lower blood pressure during an operation**

- Whilst you are under anaesthetic, 10-20mg Labetalol Injection (depending on your age and health) will be injected into your vein.
- If after five minutes your blood pressure has not been reduced, a dose of 5-10mg can be given every five minutes until your blood pressure is low enough.

### **Maintaining your blood pressure**

- After you have had Labetalol Injection your doctor may suggest you take labetalol tablets to keep your blood pressure low.
- If this applies to you, your doctor or pharmacist will tell you exactly how many tablets to take and when to take them.

### **People with liver or kidney problems:**

If you have problems with your liver or kidneys, your doctor may give you a lower dose of Labetalol Injection.

### **The elderly (65 years and over):**

Your doctor may start you on a lower dose than the usual adult dose to make sure that the medicine is working properly.

### **Children:**

Labetalol Injection is not recommended for use in children.

### **If you are given more Labetalol Injection than you should**

If you think you may have been given too much Labetalol Injection, tell your doctor immediately.

If you have any further questions about the use of this medicine, ask your doctor.

## **4. Possible side effects**

Like all medicines Labetalol Injection can cause side effects, although not everybody gets them.

### **Remember:**

**You should avoid sitting upright for three hours after being given Labetalol Injection as you may feel very dizzy and lightheaded.**

**Stop using Labetalol Injection and seek immediate medical help if you have an allergic reaction.**

**This includes any of the following symptoms:**

- **Difficulty in breathing**
- **Swelling of your eyelids, face or lips**
- **Rash or itching**

**Most of the side effects related to Labetalol Injection will wear off after the first few weeks.**

**These include:**

- headaches, tiredness or dizziness
- depression or exhaustion (lethargy)
- tingling of the scalp, or a blocked nose
- swollen ankles or sweating
- difficulty passing urine or not being able to pass urine
- not being able to ejaculate
- stomach pain, feeling sick or being sick
- the shakes after taking labetalol when pregnant
- dizziness when standing up
- low blood pressure (hypotension)
- poor circulation in the hands, cold or blue extremities, numbness or tingling of the extremities
- increase of existing leg pain on walking
- mental disturbances such as delusions and altered thought patterns, hallucinations or confusion
- sleep disturbances including nightmares
- diarrhoea
- wheezing or shortness of breath (in patients with asthma)
- the symptoms of an overactive thyroid (increased heart rate) or low blood sugar (as seen in blood test results) may be hidden
- high blood potassium levels (hyperkalaemia) especially if you have reduced kidney function

- hair loss; this may grow back after stopping treatment
- worsening of psoriasis
- heart failure causing shortness of breath with swelling of the feet and ankles
- poor blood circulation leading to cold or blue extremities with numbness or tingling in your fingers and toes
- Nipple pain
- Intermittent decrease in blood flow to your nipples, which may cause your nipples to go numb, pale, and painful (Raynaud's phenomenon)

**If any of these side effects occur, speak to your doctor immediately:**

- problems with the immune system (e.g. systemic lupus erythematosus) causing shortness of breath, joint pain, or a rash on the cheeks and arms that worsen with sun exposure
- thrombocytopenia causing nosebleeds or bleeding in the mouth or bruising because your blood does not clot as it should
- drug fever making you feel hot and flu-like
- muscle disease (toxic myopathy) causing weakness and wasting of the muscles in the arms and legs
- flat topped bumps on your skin that join up into scaly patches (lichenoid rash)
- blurred vision or dry eyes
- cramps
- liver problems or jaundice causing discomfort and tenderness in the upper abdomen, yellowing of the skin and whites of the eyes
- slowing of the heart and heart block (where the heart signals are delayed causing your heartbeat to slow to 20-40 beats per minute)
- cough or breathing problems that may indicate inflammation of the lungs (interstitial lung disease)

**Rare side effects on your baby**

If you are being treated for high blood pressure during pregnancy, your baby may suffer the following effects for a few days after birth:

- low blood pressure
- slow heartbeat
- shallow or slow breathing
- low blood sugar
- feeling cold

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via Yellow Card Scheme

Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard), or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Labetalol Injection**

Keep out of the sight and reach of children.

Do not use Labetalol Injection after the expiry date which is stated on the carton and the ampoule label. The expiry date refers to the last day of that month.

Store below 30°C.

Keep the ampoules in the original packaging in order to protect from light.

For single use only. Once opened use immediately. Discard any unused material.

Medicines should not be disposed of via wastewater or household waste.

Return any medicine you no longer need to your pharmacist.

Your doctor or nurse will make sure your medicine is correctly stored and disposed of.

## **6. Further information**

### **What Labetalol Injection contains**

- The active ingredient is labetalol hydrochloride. Each 1ml of liquid contains 5mg of the active ingredient.
- The other ingredients are dilute hydrochloric acid (E507), sodium hydroxide (E524), for pH adjustment, and water for injections.

### **What Labetalol Injection looks like**

Labetalol Hydrochloride 5mg/ml Solution for Injection is a colourless or very pale yellow solution. Labetalol Injection comes in 20ml glass ampoules, with five ampoules in each pack.

### **Marketing Authorisation Holder**

RPH Pharmaceuticals AB  
Box 603  
101 32 Stockholm  
Sweden

### **Manufacturer**

Mitim S.R.L, Via Cacciamali, 34-38 – 25125 Brescia (BS), Italy

For any information about this medicinal product, please contact the Marketing Authorisation Holder, details provided above.

**This leaflet was last revised in 02/2023**

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Technical Leaflet intended for healthcare professionals only

## **LABETALOL HYDROCHLORIDE 5mg/ml SOLUTION FOR INJECTION**

### **GENERAL INFORMATION**

Labetalol Hydrochloride 5mg/ml Solution for Injection is for single use only. Once opened, the product should be used immediately. Discard any unused material.

### **THERAPEUTIC INDICATIONS**

Labetalol Injection is indicated for the treatment of:

1. Severe hypertension, including severe hypertension of pregnancy, when rapid control of blood pressure is essential.
2. Anaesthesia when a hypotensive technique is indicated.
3. Hypotensive episodes following acute myocardial infarction.

### **POSOLOGY AND METHOD OF ADMINISTRATION**

#### **Adults:**

Labetalol Injection is intended for intravenous use in hospitalised patients. The plasma concentrations achieved after intravenous dose of labetalol in severe hypertension are substantially greater than those following oral administration of the drug and provide a greater degree of blockade of alpha-adrenoceptors necessary to control the more severe disease. Patients should, therefore, always receive the drug whilst in the supine or left lateral position. Raising the patient into the upright position, within three hours of intravenous labetalol administration, should be avoided since excessive postural hypotension may occur.

### **Bolus injection**

If it is essential to reduce blood pressure quickly, as for example, in hypertensive encephalopathy, a dose of 50mg of labetalol hydrochloride should be given by intravenous injection over a period of at least one minute. If necessary, doses of 50mg may be repeated at five minute intervals until a satisfactory response occurs. The total dose should not exceed 200mg. After bolus injection, the maximum effect usually occurs within five minutes and the effective duration of action is usually about six hours but may be as long as eighteen hours.

### **Intravenous infusion**

An alternative method of administering labetalol is intravenous infusion of a solution made by diluting the contents of two ampoules (200mg) to 200ml with Sodium Chloride and Dextrose Injection BP or 5% Dextrose Intravenous Infusion BP. The resultant infusion solution contains 1mg/ml of labetalol hydrochloride. It should be administered using a paediatric giving set fitted with a 50ml graduated burette to facilitate dosage.

#### ***In the hypertension of pregnancy:***

The infusion can be started at the rate of 20mg per hour and this dose may be doubled every thirty minutes until a satisfactory reduction in blood pressure has been obtained or a dosage of 160mg per hour is reached.

Occasionally, higher doses may be necessary.

#### ***In hypertensive episodes following acute myocardial infarction:***

The infusion should be commenced at 15mg per hour and gradually increased to a maximum of 120mg per hour depending on the control of blood pressure.

#### ***In hypertension due to other causes:***

The rate of infusion of labetalol hydrochloride should be about 2mg (2ml of infusion solution) per minute, until a satisfactory response is obtained; the infusion should then be stopped. The effective dose is usually in the range of 50-200mg depending on the severity of the hypertension.

For most patients it is unnecessary to administer more than 200mg but larger doses may be required especially in patients with pheochromocytoma. The rate of infusion may be adjusted according to the response, at the discretion of the physician. The blood pressure and pulse rate should be monitored throughout the infusion.

It is desirable to monitor the heart rate after injection and during infusion. In most patients, there is a small decrease in the heart rate; severe bradycardia is unusual but may be controlled by injecting atropine 1-2mg intravenously. Respiratory function should be observed particularly in patients with any known impairment.

Once the blood pressure has been adequately reduced, maintenance therapy with labetalol tablets should be instituted with a starting dose of one 100mg tablet twice daily (see labetalol tablet SmPC for further details). Labetalol Injection has been administered to patients with uncontrolled hypertension already receiving other hypotensive agents, including beta blocking drugs, without adverse effects.

#### ***In hypotensive anaesthesia:***

Induction should be with standard agents (e.g. sodium thiopentone) and anaesthesia maintained with nitrous oxide and oxygen with or without halothane. The recommended starting dose of Labetalol

Injection is 10-20mg intravenously depending on the age and condition of the patient. Patients for whom halothane is contra-indicated usually require a higher initial dose of labetalol hydrochloride (25-30mg). If satisfactory hypotension is not achieved after five minutes, increments of 5-10mg should be given until the desired level of blood pressure is attained. Halothane and labetalol act synergistically therefore the halothane concentration should not exceed 1-1.5% as profound falls in blood pressure may be precipitated.

Following Labetalol Injection the blood pressure can be quickly and easily adjusted by altering the halothane concentration and/or adjusting table tilt.

The mean duration of hypotension following 20-25mg of labetalol hydrochloride is fifty minutes. Hypotension induced by Labetalol Injection is readily reversed by atropine 0.6mg and discontinuation of halothane.

Tubocurarine and pancuronium may be used when assisted or controlled ventilation is required.

Intermittent Positive Pressure Ventilation (IPPV) may further increase the hypotension resulting from Labetalol Injection and/or halothane.

### **Children:**

Safety and efficacy have not been established.

### **INCOMPATIBILITIES**

Labetalol Injection has been shown to be incompatible with sodium bicarbonate injection BP 4.2% w/v.

### **STORAGE AND DISPOSAL OF LABETALOL HYDROCHLORIDE 5MG/ML SOLUTION FOR INJECTION**

Protect from light. Store below 30°C.

For single use only. Discard any unused material.

**Shelf life:** Unopened: 24 months

Once opened, the product should be used immediately.