Package leaflet: Information for the patient
Labetalol 5 mg / ml solution for injection/infusion
labetalol hydrochloride

Read all of this leaflet carefully before you start taking this medicine. It contains important information for you.
- Keep this leaflet; you may need to read it again.
- If you have further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See Section 4.

What is in this leaflet:

1. What Labetalol is and what it is used for
Labetalol contains the active substance labetalol. It is used to treat severe hypertension (high blood pressure), including severe hypertension of pregnancy (pregnancy-induced high blood pressure) when rapid control of blood pressure is necessary. Labetalol may also be used to control blood pressure during anaesthesia.
Labetalol belongs to a group of medicines called alpha and beta-blocking agents. These medicines lower blood pressure by blocking the receptors in the cardiovascular (circulatory) system, causing a decrease in blood pressure in the blood vessels far from the heart.

2. What you need to know before you are given Labetalol
Do not take Labetalol
- if you are allergic to labetalol or any of the other ingredients of this medicine (listed in section 6)
- if you have certain heart diseases for example heart block or sick sinus syndrome (unless you have a pacemaker), cardiogenic shock or heart failure which is not under control
- if you have ongoing low blood pressure
- If you have an extremely slow heart rate (severe bradycardia)
- if you have a condition known as Prinzmetal angina
- if you have asthma or a similar lung disease (obstructive airway disease).
- if you have a particular type of tumour of the adrenal gland (phaeochromocytoma), untreated with an adequate pharmacologic therapy (see section “Warning and Precautions”)

Warnings and Precautions
Talk to your doctor or pharmacist before you take Labetalol:
- if you have reduced liver function or liver damage
- if you have reduced kidney function
- if you have peripheral vascular disease for example Raynauds syndrome, intermittent claudication
- if you have diabetes mellitus (type 1 or type 2)
- if you have an overactive thyroid (thyrotoxicosis, hyperthyroidism)
- if you have previously had a severe allergic reaction (anaphylaxis) to any substance
- if you have heart failure or other problems with your heart (for example; poor left ventricular systolic function, first-degree atrio-ventricular block)
- if you know you are scheduled to have an operation
- if you have metabolic acidosis (when your body produces too much acid or when the kidneys are not

removing enough acid from your body) and phaeochromocytoma
- if you have a condition called ischaemic heart disease
- if you have any lung or respiratory system problems

If you develop a low heart rate (bradycardia) as a result of being given Labetalol, your doctor may lower your dose.

If you develop skin rashes and/or dry eyes, or any kind of allergic reaction when you are being given Labetalol, tell your doctor as they may reduce or discontinue your treatment.

Surgery
If you are having surgery requiring general anaesthetic, you must tell your surgeon ahead of your surgery that you are using Labetalol as labetalol may mask the effects of a sudden loss of blood.
Labetalol can affect your pupils during cataract surgery. Tell your eye surgeon ahead of your surgery that you are using this medication. Do not stop using labetalol before surgery unless your surgeon tells you to.

Tests
This medicine may interfere with certain medical tests/laboratory tests and possibly causing false test results. Make sure laboratory personnel and all your doctors know you use this medicine.

Children and adolescents
This medicine should not be given to children and adolescents under the age of 18.

Other medicines and Labetalol
Tell your doctor if you are taking, have recently taken or might take any other medicines before you are given Labetalol. This is especially important for the following medicines:
- NSAIDs (non-steroidal anti- inflammatory drugs) for example: sulindac or indomethacin, which are used to treat pain and inflammation
- digoxin (heart medicine)
- adrenaline which may be used to treat serious anaphylactic (allergic) reactions
- medicines for heart disorders (Class I antiarrhythmic agents, for example disopyramide and quinidine) and (Class II antiarrhythmic agents e.g. amiodarone)
- other medicines that lower the blood pressure (calcium blockers such as verapamil)
- general anaesthetics (used in surgery for narcosis)
- tricyclic anti-depressants for example; imipramine (used for the treatment of depression)
- oral antidiabetics, for example; biguanides (e.g. metformin), sulfonylureas (e.g. glimepiride), meglitinides (e.g. repaglinide), and α-glucosidase inhibitors (e.g. acarbose) which are used to lower glucose levels in the blood
- ergotamine derivates, for example; ergotamine or dihydroergotamine which are used to treat migraine
- cholinesterase inhibitors, for example donepezil, galantamine or rivastigmine which are used for the treatment of mild cognitive impairment, Alzheimer's disease and Parkinson's disease
- nitrates, antipsychotics (eg. phenothiazine derivatives, chlorpromazine) and other antipsychotics, antidepressants
- clonidine which is used to treat high blood pressure.

Pregnancy, breast-feeding and fertility
If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before you are given Labetalol. It is possible that the foetus may be affected, but Labetalol can be used when rapid control of blood pressure is necessary during pregnancy.
Labetalol is excreted in breast milk in small amounts. If you are breast-feeding, ask your doctor for advice before you are given Labetalol.
Nipple pain and Raynaud's phenomenon of the nipple have been reported (see section 4).

Driving and using machines
Not applicable.

Labetalol contains Glucose monohydrate and sodium
1 ml contains 49.5 mg Glucose monohydrate. To be considered in people with diabetes mellitus.

This medicine contains less than 1 mmol sodium (23 mg) per one ampoule of 20ml, that is to say essentially 'sodium-free'.
However, it can be diluted in sodium chloride 9 mg/ml (0.9%) solution for infusion. This should be taken into consideration for patients on a controlled sodium diet (see section INFORMATION FOR HEALTH CARE PROFESSIONALS).

3. How Labetalol is given
Labetalol should always be used as instructed by your doctor. Labetalol is intended for intravenous treatment in hospitalised patients and should be administered by healthcare personnel.
It is important that you are lying down when the injection is being given to you. You will be asked to remain lying down for three hours after you have received Labetalol as you may get dizzy (from low blood pressure) if you move to an upright position sooner than this. Labetalol can either be given as a bolus injection (where the medicine is injected directly into a vein) or an intravenous infusion (where the medicine is injected directly into a vein over a longer period of time). Your doctor will decide how Labetalol should be administered and what dose of Labetalol that you should be given.

If you are given more Labetalol than you should
Symptoms of labetalol (Labetalol) overdose include extreme dizziness when you move to an upright position (sitting or standing) and sometimes low heart rate which you will feel as a slow pulse (bradycardia).
Contact a doctor or nurse if you think you have been given too much of this medicine.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common: may affect up to 1 in 10 people
- congestive heart failure
- dizziness due to low blood pressure if you move too quickly from a lying to sitting position or from sitting to standing position (postural hypotension). This may occur within three hours after Labetalol injection and is normally temporary and occurs in the first few weeks of treatment
- congestion in your nose, which is normally temporary and occurs in the first few weeks of treatment
- raised liver function tests. This is usually reversible on withdrawal of the medicinal product
- erectile dysfunction (impotence)
- allergic reactions (hypersensitivity) may also include rash (of varying severity), itching, shortness of breath and, very rarely, fever or rapid swelling of the skin.

Uncommon: may affect up to 1 in 100 people
- tightening of the lower airways (bronchospasm)

Rare: may affect up to 1 in 1,000 people
- low heart rate, which may be felt as a low pulse (bradycardia)

Very rare: may affect up to 1 in 10,000 people
- disruption of the electrical pulses that control the heart beat (heart block)
- worsening of the symptoms of Raynaud's Syndrome (cold fingers due to impaired blood circulation)
- inflammation of the liver (hepatitis) which is usually reversible when the treatment with Labetalol is stopped
- hepatocellular jaundice (the skin and the whites of the eyes turn yellow), cholestatic jaundice (symptoms

include fatigue and nausea, followed by pruritus, dark urine and jaundice, and may include a rash or fever), and hepatic necrosis (damaged liver tissue). These symptoms are usually reversible when treatment with Labetalol is stopped

Not known (cannot be estimated from the available data)
- nipple pain
- intermittent decrease in blood flow to your nipples, which may cause your nipples to go numb, pale, and painful (Raynaud's phenomenon)

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:

United Kingdom (Northern Ireland)
The Yellow Card Scheme at
www.mhra.gov.uk/yellowcard
or search for MHRA Yellow Card in the Google Play or Apple App Store.

Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

Malta
ADR Reporting Website:
www.medicinesauthority.gov.mt/adrportal
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Labetalol
Keep this medicine out of the sight and reach of children.
This medicinal product does not require any special storage conditions.
Do not use this medicine after the expiry date which is stated on the ampoule and carton after EXP. The expiry date refers to the last day of that month.
Do not use this medicine if you notice signs of deterioration.
Chemical and physical in-use stability has been demonstrated for 24 hours at 25°C, 30°C and 40°C.
From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8 °C.

Do not throw away any medicines via wastewater or house hold waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Labetalol contains
- The active substance is labetalol hydrochloride. One ml of the solution contains 5 mg of labetalol hydrochloride.
- Other ingredients are glucose monohydrate, disodium edetate and water for injection; sodium hydroxide and hydrochloric acid (for pH adjustment).

What Labetalol looks like and contents of the pack
A clear, colourless solution in a clear glass ampoule. Each package contains 5 ampoules of 20 ml. Each ampoule contains 100 mg of labetalol hydrochloride (5 mg/ml).

Marketing Authorisation Holder and Manufacturer

S.A.L.F. S.p.A. Laboratorio Farmacologico via Marconi, 2 - 24069 Cenate Sotto (BG) - Italy - Tel. +39 035 940097

This patient information leaflet was last revised in September 2024.

INFORMATION FOR HEALTH CARE PROFESSIONALS

The following information is intended for healthcare professionals only:

Administration:

Labetalol is intended for I.V. use in hospitalised patients and should be administered by healthcare professionals. Patients should always receive the medicinal product whilst in the supine or left lateral position. Raising the patient to an upright position within 3 hours of I.V. labetalol administration should be avoided since excessive postural hypotension may occur. It is desirable to monitor the blood pressure and 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 to 2 mg intravenously. Respiratory function should be observed particularly in patients with any known impairment. Labetalol injection can either be given as a bolus injection or as an intravenous infusion. Labetalol injections have been administered to patients with uncontrolled hypertension already receiving other hypotensive agents, including beta- blocking medicinal products, without adverse effects.

Oral maintenance treatment:

Once the blood pressure has been adequately reduced by bolus injection or infusion, maintenance therapy with labetalol tablets should be substituted with a starting dose of 100 mg twice daily.

Posology: Labetalol Injection

- **Adults:**

Indication	Dose
Severe Hypertension	Bolus injection: If it is essential to reduce the blood pressure quickly a dose of 50 mg should be given by I.V. injection (over a period of at least 1 min) and, if necessary, repeated at 5 min intervals until a satisfactory response ~~is~~ occurs. The total dose should not exceed 200 mg. The maximum effect usually occurs within 5 min and the duration of action is usually about 6 h, but may be as long as 18 h.
	Intravenous infusion: A 1 mg/ml solution of labetalol should be used, i.e. the contents of two 20 ml ampoules (200 mg) diluted to 200 ml with the I.V. infusion fluids indicated in section '**Compatibility'** The infusion rate should normally be about 160 mg/h, but may be adjusted according to the response at the discretion of the physician. The effective dose is usually 50 to 200 mg, but infusion should be continued until a satisfactory response is obtained and larger doses may be needed, especially in patients with phaeochromocytoma. In case of severe hypertension of pregnancy, a slower and increasing rate of infusion should be used. Infusion rate should be started at 20 mg/h, then doubled every 30 minutes until a satisfactory response is obtained or a dosage of 160 mg/h is reached.

Achieving controlled hypotension during anaesthesia	To achieve controlled hypotension during anaesthesia, the recommended starting dose of labetalol for injection is 10 to 20 mg intravenously depending on the age and condition of the patient. If satisfactory hypotension is not achieved after 5 min, increments of 5 to 10 mg should be given until the desired level of blood pressure is attained. The mean duration of hypotension following 20 to 25 mg of labetalol is 50 min.

Hypertension Due to Other Causes	Infuse at a rate of 120-160 mg/h until a satisfactory response is obtained, then stop infusion. The effective dose is usually 50 to 200 mg but larger doses may be needed, especially in patients with phaeochromocytoma

- **Paediatric population:**

The safety and efficacy of labetalol in paediatric patients aged 0 to 18 years have not been established. No data are available.

Compatibility:

Labetalol should be diluted only with compatible I.V. infusion fluids under aseptic condition.

Labetalol injection is compatible with the following I.V. infusion fluids:

- 5 % Dextrose BP
- 0.18 % Sodium Chloride and 4 % Dextrose BP
- 0.3 % Potassium Chloride and 5 % Dextrose BP
- Compound Sodium Lactate BP (Ringer Lactate)
- 0.9 % Sodium Chloride

Incompatibilities:

Labetalol injection has been shown to be incompatible with Sodium Bicarbonate injection BP 4.2 % W/V.

Overdose:

Symptoms and signs:
Profound cardiovascular effects are to be expected, e.g. excessive, posture-sensitive hypotension and sometimes bradycardia. Oliguric renal failure has been reported after massive overdosage of labetalol orally. In one case, the use of dopamine to increase the blood pressure may have aggravated the renal failure.

Treatment:
Patients should be laid supine with the legs raised. Parenteral adrenergic/anticholinergic therapy should be administered as needed to improve circulation.
Haemodialysis removes less than 1% labetalol hydrochloride from the circulation.