Package leaflet: Information for the user

Labetalol Tablets 100 mg, 200 mg and 400 mg

(Labetalol Hydrochloride)

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may want to read it again.
- If you have further questions, please 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.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. **What Labetalol Tablets are and what they are used for**
2. **Before you take Labetalol Tablets**
3. **How to take Labetalol Tablets**
4. **Possible side effects**
5. **How to store Labetalol Tablets**
6. **Further information**

1. What Labetalol Tablets are and what they are used for

The active ingredient of these tablets, labetalol, belongs to a group of medicines known as adrenergic blocking agents which are used for the treatment of hypertension (high blood pressure) and angina (chest pain).

Labetalol Tablets are used to treat high blood pressure. They are also used to treat angina in patients who also have high blood pressure.

2. Before you take Labetalol Tablets

Do not take Labetalol Tablets if any of the following applies to you:
- An allergy to labetalol or any of the other ingredients in this medicine (see section 6 ‘Further information’).
- Heart shock (cardiogenic shock); your heart is unable to supply enough blood to your body.
- Uncontrolled heart failure.
- Heart block (your blood pressure is very low for a long time or your heart beats very slowly e.g. second or third degree heart block).
- Chest pain (angina), either at rest or after vigorous action/effort.
- Wheezing, obstructive airways disease or asthma.
- A tumour of the adrenal gland (phaeochromocytoma); your doctor will tell you if you have this.
- Metabolic acidosis, a condition where there are more acid waste products than normal in your blood.

- Slow heart beat (less than 45 or 50 beats a minute).
- Low blood pressure (hypotension).
- Poor circulation.

Take special care with Labetalol Tablets
Tell your doctor if any of the following applies to you:
- Heart problems, e.g. a weak heart, poor blood supply to the heart, digitalis-resistant heart failure or atrio-ventricular block.
- You are about to have an anaesthetic; you must always tell the anaesthetist or doctor before you have an anaesthetic.
- A circulatory problem (such as Raynaud's disease).
- Jaundice (yellowing of the skin and whites of the eyes) or liver problems.
- Kidney problems.
- A history of psoriasis.
- A history of severe allergic reactions.
- You are elderly
- You are receiving a procedure called MIBG scintigraphy (often used to detect certain tumours)

Treatment should NOT be suddenly discontinued, especially if you have a disease of the heart caused by a failure in the blood supply (ischaemic heart disease).

Labetalol can affect the results of **blood tests** to check your liver function. If you are going to have such a test tell your hospital or surgery that you are taking labetalol.

Taking other medicines
Please tell your doctor if you are taking or have recently taken any other medicines, including those obtained without a prescription.

In particular, tell your doctor if you are taking:
- Medicines for your heart or blood pressure e.g. digitalis, clonidine, hydralazine, disopyramide, quinidine, amiodarone, calcium antagonists such as verapamil, diltiazem, nifedipine.
- Drugs for depression such as monoamine oxidase inhibitors and tricyclic antidepressants, barbiturates and phenothiazines.
- Pain killers such as aspirin.
- Drugs which stimulate the activity of the sympathetic nervous system such as salbutamol.
- Cimetidine, a drug for stomach ulcers.
- Insulin or oral antidiabetic drugs.
- Prostaglandin synthetase inhibiting drugs - your doctor will tell you if you are taking these.

Please tell the hospital doctor, anaesthetist or dentist, that you are taking labetalol. This is important if you are going to have an operation involving a general anaesthetic.

Taking Labetalol Tablets with food and drink
These tablets should be taken with food.
Do not drink alcohol whilst taking labetalol as it can interfere with the usual effect of the medicine.

Pregnancy, breast-feeding and fertility
Labetalol should only be taken in the first three months of pregnancy if considered essential by your doctor.
Labetalol passes into breast milk. Breast-feeding whilst taking labetalol is not recommended.
Nipple pain and Raynaud's phenomenon of the nipple have been reported (see section 4).
Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
Labetalol may make you feel sleepy and/or dizzy. If affected, do not drive or operate any tools or machines whilst taking this medicine.

Important information about some of the ingredients of Labetalol Tablets
- This medicine contains **Lactose**. If you have been told by your doctor you have an intolerance to lactose or some sugars contact your doctor before taking Labetalol Tablets.
- This medicine also contains **propyl hydroxybenzoate** (E216) and **methyl hydroxybenzoate** (E218) which may cause allergic reactions (possibly delayed).

3. How to take Labetalol Tablets
These tablets should be taken with food. The normal dose of Labetalol Tablets is as follows:

Adults: When you are prescribed these tablets for the first time, your doctor will prescribe one 100 mg tablet twice a day (every 12 hours). Depending upon your response your doctor may increase your dosage, usually every 2 weeks, although this may be more frequently if you are in hospital, until your condition has stabilised. A total daily dose of 800mg may be taken (in very severe cases doses as high as 2,400mg may be given in which case you will probably be told to take your tablets 3 or 4 times a day).

You may be given other medicines along with labetalol to help control your blood pressure, and these, together with the labetalol, will have a combined effect.

Elderly Patients: An initial dose of 50mg twice daily is recommended.

Children: Not recommended.

You should always follow your doctor's instructions on taking your medicine.
Your doctor will tell you how long your treatment with Labetalol Tablets will last. Do not stop treatment early (see section below on "If you stop taking Labetalol Tablets").
If you have the impression that the effect of labetalol is too strong or too weak, talk to your doctor or pharmacist.

If you take more Labetalol Tablets than you should
If you have taken more tablets than you should, talk to your doctor or local hospital accident and emergency department.

If you forget to take Labetalol Tablets
Do not take a double dose to make up for forgotten individual doses. If you have forgotten to take your medicine, take it as soon as you remember. If your next dose is due within 2 hours, take the dose now and skip the next one.

If you stop taking Labetalol Tablets
DO NOT stop taking the tablets until the doctor has told you to. It can be dangerous to suddenly stop taking them, especially if you have ischaemic heart disease. The dosage should gradually be reduced, over 1-2 weeks, if necessary at the same time starting replacement treatment to prevent a worsening of chest pain (angina pectoris). In addition, high blood pressure and changes in the rhythm of the heart beat may develop.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines Labetalol Tablets can have side effects, although not everybody gets them.

The following side effects have been reported **rarely**:
- **Allergic reactions (rash, itching, swelling, difficulty breathing).**
- Problems with the normal function of the body's immune system.
- Slowing of the heart and heart block (where the heart signals are delayed).
- Other rashes.
- Liver problems, including jaundice.

The following side effects have been reported **very rarely**:
- Drug fever (you may feel hot and flu-like).
- Muscle disease (toxic myopathy); you may experience muscle cramps, stiffness, and/or spasm.

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)

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the above effects.
Tell your doctor if you experience any of the following side effects, which should **wear off** in the first few weeks:
- headache
- tiredness
- depression
- lethargy
- dizziness
- sweating
- blocked nose
- swollen ankles
- tingling of the scalp
- feeling faint or dizzy on standing up
- difficulty in passing urine
- ejaculatory problems
- stomach pain
- feeling sick
- being sick

Other possible side effects include:
- heart failure
- cold or blue extremities
- poor blood circulation to leading nipple pain, cold or blue extremities with numbness or tingling in your fingers and toes
- a numbness/tingling sensation in the fingers and toes (paraesthesia)
- increase of existing leg pain on walking
- hallucinations
- mental disturbances
- confusion
- sleep disturbances
- nightmares
- diarrhoea
- wheezing or shortness of breath (in patients with asthma)
- masking of the symptoms of high thyroid hormone or low blood sugar level.

Reports of other effects, which may be related to drugs like labetalol include:
- blurred vision
- dry eyes
- cramps

Tell your doctor if you experience any of these effects.

Pregnancy
- Tremor has been reported in pregnant women after taking Labetalol Tablets.

Tell your doctor if you experience this effect.

Taking labetalol during pregnancy may cause problems to your baby when it is born. The following effects have been reported:
- slow heart rate
- low blood pressure
- breathing problems
- low blood sugar level
- low body temperature

These effects are rare and the baby will usually respond quickly to treatment.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Labetalol Tablets

Keep out of the reach and sight of children.

Keep this medicine in a cool dry place and protect from light.

Do not use Labetalol Tablets after the expiry date which is stated on the blister or carton. The expiry date refers to the last day of that month.
Do not use Labetalol Tablets if you notice any defects such as chips or discolouration, take them to your pharmacist for advice.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

What Labetalol Tablets contain
The **active** substance is labetalol hydrochloride. Each tablet contains 100 mg, 200 mg or 400 mg of labetalol hydrochloride.
Other ingredients include: lactose, maize starch, magnesium stearate, hydroxypropyl methylcellulose, colour containing titanium dioxide (E171) and sunset yellow (E110), methyl hydroxybenzoate (E218), propyl hydroxybenzoate (E216).

What Labetalol Tablets look like
Labetalol Tablets 100mg are orange, circular, biconvex, film-coated tablets engraved with ‘100 LAB’ on one side and plain on the other.

Labetalol Tablets 200mg are orange, circular, biconvex, film-coated tablets engraved with ‘200 LAB’ on one side and plain on the other.

Labetalol Tablets 400mg are orange, circular, biconvex, film-coated tablets engraved with ‘400 LAB’ on one side and plain on the other.

Labetalol Tablets are supplied in blister pack sizes of 56 tablets.

Marketing Authorisation Holder and Manufacturer
Sandoz Ltd, 37 Woolmer Way, Bordon, Hampshire, GU35 9QE.

This leaflet was last revised in: 06/2022