

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Labetalol 100mg and 200mg Film-coated Tablets

(Labetalol Hydrochloride)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. 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
2. What you need to know before you take Labetalol
3. How to take Labetalol
4. Possible side effects
5. How to store Labetalol
6. Contents of the pack and other information

1 What Labetalol is and what it is used for

Labetalol belongs to a group of medicines called beta-blockers, which help slow the heartbeat and relax the blood vessels. This reduces blood pressure.

Labetalol is used to treat the following:

- High blood pressure (hypertension)
- High blood pressure during pregnancy
- High blood pressure in patients with chest pain (angina)

2 What you need to know before you take Labetalol

Do not take Labetalol if:

- **You have a history of breathing difficulties, wheezing or asthma**
- You are allergic to Labetalol, other beta-blockers or any of the other ingredients of this medicine (listed in section 6)
- You have very low blood pressure (hypotension) or you have had this condition for a long time e.g. due to a weakened heart (cardiogenic shock)
- You have a slow heart rate (less than 45 – 50 beats per minute) (bradycardia)
- You have an irregular or slower heartbeat than normal (2nd or 3rd degree heart block)
- You have shortness of breath, feel tired or ankle swelling (heart failure), which is not controlled by medicine or does not respond to treatment with digitalis
- You have an irregular heartbeat (sick sinus syndrome) or had dizziness, weakness or confusion (sino-atrial block)
- You have chest pains when at rest (Prinzmetal's angina)
- You have severe circulation problems, which make the toes and fingers go numb
- You have an untreated rare tumour of the adrenal gland (phaeochromoytoma)
- You have more acid than normal in your blood (metabolic acidosis)

Warnings and precautions

Talk to your doctor before taking Labetalol if:

- Your heart has difficulty pumping blood around your body (low cardiac reserve) or you suffer from shortness of breath or ankle swelling (heart failure)
- Your heartbeat slows to less than 50–55 beats per minute whilst resting (bradycardia)
- You have circulatory problems such as your toes and fingers go numb and pale (Raynaud's syndrome) or you sometimes limp (intermittent claudication)
- You have irregular heartbeat (first degree heart block)
- You have a poor flow of blood to your heart (ischaemic heart disease)
- You have liver or kidney problems
- You are elderly, particularly if you have kidney problems

- You have a skin disease which causes scaly pink patches (psoriasis)
- You have any allergies
- You are due to have an anaesthetic or cataract surgery (see 'Having an anaesthetic or cataract surgery' section)

Other medicines and Labetalol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those obtained without prescription. This includes herbal medicines.

Medicines which **should not be taken** with Labetalol:

- Calcium channel blockers for high blood pressure or chest pain (angina), such as verapamil and, to a lesser extent, diltiazem
- Medicines for heart failure or irregular heartbeat, such as digoxin (digitalis glycosides)
- Medicines for depression, such as moclobemide (Monoamine Oxidase Inhibitors – MAOIs)
- Clonidine, used to treat high blood pressure and migraine. Labetalol should be stopped several days before you stop taking Clonidine.

Other medicines which **may interact with or be affected** by Labetalol:

- Medicines for irregular heartbeat, such as disopyramide, quinidine and amiodarone (class I antiarrhythmics)
- Medicines for diabetes, such as metformin and insulin. Labetalol may increase the effects of low levels of sugar in your blood (hypoglycaemia) and hide the warning signs such as shaking (tremors) and faster heartbeat (tachycardia)
- Cimetidine, for stomach ulcers and indigestion
- Hydralazine, for high blood pressure
- The following groups of medicines may **increase** the blood pressure lowering effect of Labetalol:
 - ACE inhibitors, angiotensin-II antagonists and alpha blockers, used to treat high blood pressure
 - Aldesleukin, used to treat some cancers
 - Alprostadil, used to treat sexual disorders such as impotence
 - Medicines used to treat anxiety e.g. diazepam (anxiolytics)
 - Medicines used to treat sleep problems e.g. zolpidem (hypnotics)
 - Moxisylyte, used to treat poor circulation
 - Medicines used to increase frequency of urination e.g. furosemide (diuretics)
- The following groups of medicines may **decrease** the blood pressure lowering effect of Labetalol:
 - Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), and corticosteroids, used to treat pain and inflammation such as ibuprofen
 - Hormones such as oestrogen and progesterone, used as contraceptives or Hormone Replacement Therapy (HRT)
- Other medicines for high blood pressure or chest pains (angina), including calcium antagonists, such as nifedipine
- Medicines for reducing inflammation, relieving pain, swelling and stiffness in the joints and muscles, such as indomethacin (prostaglandin synthetase inhibitors)
- Medicines used to treat severe allergic reactions such as adrenaline (sympathomimetics)
- The following groups of medicines may increase the frequency of shaking (tremor) and the blood pressure lowering effect of Labetalol:
 - Tricyclic antidepressants for depression, such as amitriptyline
 - Barbiturates for epilepsy, sleeping disorders and Parkinson's disease such as phenobarbital
 - Phenothiazines for anxiety, mental disorders, feeling and/or being sick (nausea, vomiting) such as trifluoperazine
 - Other medicines used to treat high blood pressure (antihypertensives)
- Anti-malarial medicines such as mefloquine or quinine
- Medicines used to treat migraine such as ergotamine

Having an anaesthetic or cataract surgery

You must tell the medical staff that you are taking Labetalol if you are going to have surgery under anaesthetic or cataract surgery.

Anaesthetics may interfere with this medicine, in particular anaesthetics such as cyclopropane, trichloroethylene.

Having a laboratory test

This medicine is known to interfere with the results of catecholamine testing and MIBG scans (tests for diagnosing a tumour in the adrenal glands).

Taking Labetalol with food and drink and alcohol

- These tablets should be taken with food
- It is recommended that you do not drink alcohol whilst being treated with Labetalol.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Pregnancy

This medicine should not be taken during the first 3 months of pregnancy (first trimester) unless your doctor thinks the benefits outweigh the risks.

Breast-feeding

If you are breast-feeding, you should not take Labetalol as it passes into breast milk. Nipple pain and Raynaud's phenomenon of the nipple have been reported (see section 4).

Driving and using machines

Labetalol may make you feel tired or dizzy. If this happens, do not drive or operate machinery.

Labetalol contains lactose

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.

Labetalol contains the colouring agent sunset yellow FCF (E110)

It may cause allergic reactions.

3 How to take Labetalol

Always take Labetalol exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- These tablets are to be taken orally.
- These tablets should be taken with food.

High blood pressure with or without chest pain (angina)

- The usual starting dose is 100mg twice daily.
- Your doctor may increase this dose by 100mg twice daily every 14 days.
- For severely high blood pressure, a daily dose of 2400mg may be prescribed, to be taken in three or four divided doses.

High blood pressure in pregnancy

- The usual starting dose is 100mg twice daily.
- This may be increased each week by 100mg twice daily.
- During the second and third trimesters (months 4 – 9), the dose may be increased further ranging from 100mg-400mg three times daily.
- The maximum dose is 2400mg daily, to be taken in three or four divided doses.
- If admitted to hospital, the dose may be increased daily, if required.

General

- If a rapid reduction in blood pressure is required, you may be given Labetalol by injection.

Elderly

The usual starting dose is 50mg twice a day.

Use in children

Children should not take Labetalol.

If you take more Labetalol than you should

If you accidentally take too many tablets, contact your doctor or nearest hospital emergency department **immediately** for advice. Remember to take this leaflet or any remaining tablets with you, **Symptoms of overdose include:** low blood pressure (hypotension), slower heartbeat (bradycardia), difficulty in breathing or wheezing (bronchospasm) and sudden heart failure (acute cardiac insufficiency)

If you forget to take your Labetalol

Take it as soon as you remember, unless it is nearly time for your next dose. If you miss a dose, do **not** take a double dose to make up for a forgotten dose.

If you stop taking Labetalol

It is important that you keep taking Labetalol for as long as your doctor has told you to. Your doctor will gradually reduce your dose before you stop taking this medicine. If you do not gradually reduce your dose you may develop high blood pressure and an irregular heartbeat

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

4 Possible side effects

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

Seek medical advice immediately if you develop the following symptoms:

- Allergic reactions: swelling of the face, throat or tongue, difficulty breathing or dizziness
- Difficulty breathing (if you have asthma or a history of asthma)
- Hypersensitivity (rash, severe itching [pruritus], swelling of the deeper layers of the skin caused by a build-up of fluid [angioedema], shortness of breath or difficulty in breathing [dyspnoea])

Side effects

- Headache
- A lack of energy (lethargy)
- Tiredness
- Depression
- Dizziness
- Blocked nose
- Sweating
- Tingling scalp
- Swollen ankles
- Slower heartbeat (bradycardia)
- Positive autoimmune blood tests
- Irregular or slower heartbeat than normal (heart block)
- Long-term inflammation of skin and/or intestines (Systemic Lupus Erythematosus [SLE])
- Liver failure or damage (hepatic necrosis)
- Increase in liver enzymes (detected through blood test)
- Yellowing of the skin or whites of the eyes (jaundice)
- Inflammation of the liver (hepatitis)
- Medicine-induced fever
- Pain or weakness in the muscles (toxic myopathy)
- Feeling (nausea) or being sick (vomiting)
- Stomach pain
- Poor vision
- Dry eyes
- Confusion
- Sleep disturbances
- Nightmares
- Diarrhoea
- Feeling light-headed and dizzy when you get up from sitting or lying down (postural hypotension) (usually due to the initial dose being too high or increases in doses being too rapid)

- Unable or difficult to urinate
- Shaking (tremor) during pregnancy
- Difficulty for men to ejaculate
- Heart failure
- Poor blood circulation leading to nipple pain, cold or blue extremities with numbness or tingling in your finger and toes
- Seeing or hearing things that are not real (hallucinations)
- Mental illness (psychoses)
- Hiding the symptoms of high levels of thyroid hormones in the blood (thyrotoxicosis)
- Hiding the symptoms of low blood sugar levels (hypoglycaemia)
- Increase of existing cramping pain in the calf, thigh or buttocks (intermittent claudication)
- Abnormally high levels of potassium in blood (hyperkalaemia)
- A reduction in blood platelets, which increases risk of bleeding or bruising (thrombocytopenia)
- Low blood pressure (hypotension)
- Inflammation of the lungs (interstitial lung disease)
- (Reversible) non-infectious, itchy rash that can affect many areas of the body (lichenoid rash)
- Worsening of psoriasis (skin disease causing scaly pink patches)
- Cramps
- (Reversible) hair loss (alopecia)

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at 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

- Keep this medicine out of the sight and reach of children.
- Do not use Labetalol after the expiry date, which is stated on the carton after EXP. The expiry date refers to the last day of that month.
- Store in the original package in order to protect from moisture.
- Medicines should not be disposed of via wastewater or household 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:

- Each 100mg tablet contains Labetalol Hydrochloride 100mg
- Each 200mg tablet contains Labetalol Hydrochloride 200mg

The other ingredients are: lactose, starch, povidone, isopropanol, sodium starch glycollate, magnesium stearate. Coating: hydroxypropyl methylcellulose, sunset yellow (E110), triacetin, water, IMS.

What Labetalol looks like and content of the pack:

- Labetalol 100mg are orange, round, biconvex, film-coated tablets coded 'LTL 100' on one side
- Labetalol 200mg are orange, round, biconvex, film-coated tablets coded 'LTL 200' on one side

Labetalol is available in:

Labetalol Tablets are available in containers or blister packs of 7, 14, 21, 28, 30, 50, 56, 60, 84, 90, 100, 112, 120, 250, 500 or 1000 tablets

Not all pack sizes or pack types may be marketed.

Product Licence Numbers:

- Labetalol 100mg Tablets: PL 11311/0375
- Labetalol 200mg Tablets: PL 11311/0376

Marketing Authorisation Holder:

Tillomed Laboratories Ltd
220 Butterfield
Great Marlings
Luton
LU2 8DL
UK

Manufacturer

Kleva Pharmaceuticals S.A
189 Parnithos Ave
13675 Acharnai-Attiki
Greece

This leaflet was last revised in January 2022

Till Ver.12