

Trandate Tablets 100mg

Labetalol hydrochloride (100mg)

What is in the leaflet?

1. What Trandate Tablet is used for
2. How Trandate Tablet works
3. Before you use Trandate Tablet
4. How to use Trandate Tablet
5. While you are using it
6. Side effects
7. Storage and Disposal of Trandate Tablet
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of RiMUP revision

What Trandate Tablet is used for

Trandate Tablet is used for the treatment of all degrees of hypertension. Hypertension is a condition marked by high blood pressure.

How Trandate Tablet works

Trandate Tablet contains a medicine called labetalol hydrochloride. This belongs to a group of medicines called beta-blockers. It works by changing the body's response to some nerve impulses. Therefore, it widens the blood vessels in the body, causing the blood pressure to fall.

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

Before you use Trandate Tablet

- When you must not use it

Do not take this medicine if you have an allergy to:

- labetalol hydrochloride, the active ingredient
- any of the other ingredients listed at the end of this leaflet

Do not take Trandate Tablet if

- you suffer from second or third degree heart block (unless pacemaker is in situ), cardiogenic shock and other conditions accompanied by severe and prolonged hypertension or bradycardia.
- you suffer from asthma or from airways obstruction.
- you suffer from uncompensated heart failure
- you suffer from unstable / uncontrolled heart insufficiency
- you suffer from sick sinus syndrome (including sinus atrial block) unless pacemaker is in situ.
- you suffer from Prinzmetal angina.
- you suffer from sinus node dysfunction.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

- Before you start to use it

Tell your doctor if you have allergies to any other

medicines, foods, preservatives or dyes.

Tell your doctor if you have intolerance to some sugars as Trandate Tablet contains lactose.

Before you take Trandate Tablet, tell your doctor or pharmacist if:

- you are pregnant or breastfeeding.
- you suffer or have suffered in the past from impaired function of: the respiratory system, the heart and / or vascular system, liver or the kidney.
- you suffer from diabetes mellitus, thyrotoxicosis, metabolic acidosis, pheochromocytoma.
- You have experienced intraoperative floppy iris syndrome.

If you have not told your doctor any of the above, talk to he/she before taking Trandate Tablet.

- Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Trandate Tablet may interfere with each other.

These include:

- Prostaglandin synthesis inhibitors (NSAIDs)
- Tricyclic anti-depressants
- Halothane
- Cimetidine

- Calcium channel blockers (e.g. verapamil, diltiazem, nifedipine)
- Class-I antiarrhythmics agents (e.g. disopyramide and quinidine)
- Amiodarone
- Digoxin
- Adrenaline
- Beta stimulating adrenergics
- Ergotamine Derivates
- Nitrates
- Antipsychotics (e.g. Chlorpromazine)
- Cholinesterase inhibitors
- Radioisotopes of metaiodobenzylguanidine

These medicines may be affected by Trandate Tablet or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

If you 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 this medicine.

How to use Trandate Tablet

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

These directions may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

- How much to use

Always take Trandate Tablet exactly as your doctor has told you.

The dose of Trandate Tablet depends on your condition.

The starting dose is 100mg twice daily. If necessary, increase the dosage to 800mg daily (as twice daily regimen). In severe cases, daily doses up to 2400mg have been given.

- When to use it

Take each dose of Trandate Tablet at about the same time each day.

Taking each dose of Trandate Tablet at the same time each day will have the best effect. It will also help you to remember when to take the medicine.

Take Trandate Tablet with meal.

- How long to use it

Continue taking Trandate Tablet for as long as your doctor recommends.

- If you forget to use it

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 it 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 that you missed.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

- If you use too much (overdose)

Immediately telephone your doctor for advice or go to Accident and Emergency (Casualty) at your nearest hospital if you think that you or anyone else may have taken too much Trandate Tablet.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using Trandate Tablet

- Things you must do

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

Tell your doctor if you are pregnant, plan to become pregnant or breast-feeding.

If you are about to start taking any new medicine tell your doctor and pharmacist that you are taking Trandate Tablet.

- Things you must not do

Do not stop taking your medicine abruptly especially if you have ischaemic heart disease, heart failure or angina pectoris, or lower the dosage without checking with your doctor.

Do not take Trandate Tablet to treat any other complaints unless your doctor tells you to.

Do not give your medicine 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 Trandate Tablet affects you.

Side effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

Ask for the advice of your doctor or pharmacist if you have any concerns about the effects of taking this medicine.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Some of the common side effects include:

- Skin rash
- Postural hypotension
- Blocked nose
- Difficulty passing urine
- Dizziness
- Headache
- Blurred vision
- Nausea
- Erectile dysfunction
- Congestive heart failure

Other side effects not listed above may also occur in some people.

Frequency not known (cannot be determined from the available data) side effects include:

- Nipple pain and intermittent decrease in blood flow to your nipples, which may cause your nipples to go numb, pale and painful (Raynaud's phenomenon)
- High blood potassium levels (hyperkalaemia) especially if you have reduced kidney function

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction

Monitoring by visiting the website npa.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Trandate Tablet

- Storage

Keep your medicine in its original packaging until it is time to take them.

If you take the tablets out of the pack, they may not keep well.

Keep your medicine in a place where the temperature stays below 30°C.

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

Keep it where children cannot reach it.

- Disposal

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.

Product Description

- What it looks like

Orange, round, biconvex film-coated tablets, engraved TT01 on one face.

- Ingredients

Active ingredient:

- Labetalol hydrochloride

Inactive ingredients:

- Cellulose Microcrystalline
- Lactose anhydrous
- Magnesium stearate

- Opadry orange

- MAL number

MAL06011677AZ

Manufacturer

Aspen Bad Oldesloe GmbH, Industriestrasse 32 – 36, 23843, Bad Oldesloe, Germany.

Product Registration Holder

Aspen Medical Products Malaysia Sdn Bhd
201201020269 (1004761-W)
Unit 1302A, Level 13A, Uptown 1, 1 Jalan SS21/58, Damansara Uptown, 47400 Petaling Jaya, Selangor, Malaysia.

Date of Revision

01 May 2026

Serial Number

NPRA(R1/2) 01072022/213