

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

TRANDATE TABLETS TRANDATE TABLETS

100 mg

200 mg

The active ingredient and its quantity:

Each tablet contains:

Labetalol Hydrochloride 100 mg

Labetalol Hydrochloride 200 mg

Inactive ingredients and allergens in the preparation – see section 2 "Important information about some of the ingredients of the medicine" and section 6 "Additional Information" in the leaflet.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their illness is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

A medicine for the treatment of all grades of hypertension.

Therapeutic group: Alpha and beta blockers.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient, labetalol hydrochloride, or to any of the other ingredients contained in this medicine (see section 6).
- You have certain heart conditions (such as second or third degree heart block, unless you have a pacemaker; untreated heart failure).
- You have low blood pressure.
- You have an extremely slow heart rate (severe bradycardia).
- You have Prinzmetal angina (variant angina).
- You have asthma or a similar lung disease (obstructive airway disease).

Special warnings regarding use of the medicine

Before treatment with Trandate, tell the doctor if:

- You have impaired liver function or liver disease
- You have impaired kidney function
- You have vascular disease, such as Raynaud's syndrome, intermittent claudication
- You have type 1 or type 2 diabetes mellitus
- You have an overactive thyroid gland (thyrotoxicosis – increased concentration of thyroxin for any reason, hyperthyroidism)
- You have previously had a severe allergic reaction (allergic shock) to any substance
- You have heart failure or other heart diseases [such as: impaired systolic function (contractility) in the left ventricle of the heart or first degree atrioventricular block]
- You are scheduled to undergo any surgery
- You have metabolic acidosis (when your body produces too much acid or when your kidneys do not remove enough acid from your body)
- You have pheochromocytoma (a particular type of tumor in the adrenal gland)
- You have a condition called ischemic heart disease

If you have a low heart rate (bradycardia) as a result of taking Trandate, your doctor may lower the dosage of the medicine.

If you develop a skin rash and/or dry eyes or any allergic reaction while taking the medicine, tell the doctor, who may recommend that you decrease your dosage or stop the treatment. Always follow the doctor's instructions.

Do not stop treatment with the medicine suddenly, especially if you have a heart disease (ischemic heart disease or angina pectoris). Refer to your doctor if you think you should stop the treatment with the medicine.

Surgery

If you are to undergo surgery with general anesthesia, you must inform the surgeon that you are taking Trandate before the operation. Labetalol can affect your pupils during eye (cataract) surgery; therefore, you should tell the surgeon that you are using this medicine before the operation. Do not stop using the medicine before the operation unless the surgeon instructed you to do so.

Drug interactions

If you are taking, have recently taken or might take other medicines, including non-prescription medicines and nutritional supplements, tell your doctor or pharmacist, especially if you are taking:

- Non-steroidal anti-inflammatory or anti-rheumatic drugs (NSAIDs) which are used to treat pain and inflammation (such as sulindac or indomethacin)
- Digoxin (to treat heart diseases)
- Adrenaline (to treat severe anaphylactic (allergic) reactions)
- Medicines for treatment of heart problems (class I antiarrhythmics such as disopyramide and quinidine, and class II antiarrhythmics such as amiodarone)
- Other medicines to reduce blood pressure (calcium channel blockers such as verapamil)
- Tricyclic antidepressants to treat depression (such as imipramine)
- Medicines to treat stomach ulcer or heartburn (such as cimetidine)
- Oral antidiabetics intended to reduce blood sugar level, such as: biguanides (e.g., metformin), medicines of the sulphonylurea group (e.g., glibenclamide), meglitinides (e.g., repaglinide), and alpha-glucosidase inhibitors (e.g., acarbose)
- Medicines to treat migraine such as ergotamine derivatives (e.g., ergotamine or dihydroergotamine)
- Medicines to treat mild cognitive disorders, Alzheimer's disease and Parkinson's disease – cholinesterase inhibitors, such as: donepezil, galantamine or rivastigmine
- Nitrates, antipsychotics (e.g., phenothiazines, chlorpromazine) and antidepressants
- Clonidine (to treat hypertension)

Medical tests

The medicine can affect the results of certain medical tests or laboratory tests and lead to incorrect test results.

Before undergoing medical tests or laboratory tests, inform the medical staff that you are taking Trandate.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you might be pregnant or are planning to become pregnant, consult the doctor before taking this medicine.

It is possible that the fetus may be affected, but the medicine can be used during pregnancy if it is necessary.

The medicine is excreted in small quantities in breast milk. Nipple pain and Raynaud's phenomenon of the nipple have been reported (see section 4). If you are breastfeeding, consult the doctor before using Trandate.

Driving and using machines

It is not likely that Trandate will affect the ability to drive or use machines. Some individuals may, however, experience dizziness and/or fatigue. You should be aware that this can affect your ability to react and you should therefore be cautious until you have become accustomed to your reaction to the medicine.

You alone are responsible for deciding if you are in a fit condition to drive a motor vehicle or perform other tasks that demand increased concentration. Because of their effects and/or side effects, one of the factors that can reduce your ability to perform these actions is your use of medicines. Descriptions of these effects and other side effects can be found in other sections. Read all the information in this leaflet for guidance. Discuss with your doctor or pharmacist if you are unsure.

Important information about some of the ingredients of the medicine

• Trandate tablets contain lactose.

If you have difficulty tolerating certain sugars, refer to the doctor before using the medicine.

• Trandate tablets contain Sunset yellow FCF (E110).

This may cause an allergic reaction.

• Trandate tablets contain sodium benzoate

Trandate tablets 100 mg contain 1.15 micrograms benzoate in each tablet.

Trandate tablets 200 mg contain 2.30 micrograms benzoate in each tablet.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the medicine according to the doctor's instructions.

Check with the doctor or pharmacist if you are unsure about the dosage and treatment regimen of the medicine.

The dosage and treatment regimen will be determined by the doctor only.

The doctor may recommend a lower dosage for elderly patients or patients with impaired liver function.

Do not exceed the recommended dose

Take the medicine with food.

Do not chew, halve or crush the tablet due to lack of supporting data.

If you have accidentally taken a higher dosage

The symptoms of overdose of the medicine include extreme dizziness when you change position from sitting to standing or from lying down to sitting, and sometimes a slowing of the heart rate (which is felt as a slow pulse – bradycardia).

If you have taken an overdose or if a child or someone else has swallowed the medicine by accident, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forget to take the medicine

If you forgot to take this medicine at the designated time, do not take a double dose. Consult the doctor or pharmacist if you are not sure. Adhere to the treatment regimen as recommended by the doctor. Even if there is an improvement in your health condition, do not stop treatment with the medicine without consulting the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them. If you have further questions regarding the use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, the use of Trandate can cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Refer to the doctor immediately if any of the following symptoms appear (very rare and appear in less than one in 10,000 users):

- Systemic lupus erythematosus, which causes symptoms such as: joint pain, fever, skin rash and fatigue
- Complete inability to urinate despite a full bladder (this situation is a medical emergency)
- Angioedema (allergic edema) that may cause symptoms including swollen lips, face and tongue, which may result in breathing difficulties

Additional side effects

Very common side effects – appear in more than one in ten users:

- Antibodies not associated with illness.

Common side effects – appear in 1-10 in 100 users:

- Heart failure
- Elevated liver function tests. These usually return to normal once you have stopped treatment with the medicine
- Dizziness, headache and a tingling sensation in the scalp, which are usually transient and may occur during the first weeks of treatment
- Blurred vision
- Difficulties urinating
- Dizziness due to low blood pressure if you move too quickly from a lying to a sitting position, or from a sitting to standing position (postural hypotension). This condition is more common with very high doses or if the starting dose is too high or the dose is increased too rapidly. These effects are usually transient and may occur during the first weeks of treatment
- Nasal congestion, which is usually transient and may occur during the first weeks of treatment
- Nausea
- In men: erectile dysfunction (impotence) and ejaculation problems
- Fatigue and lack of energy – usually transient and may occur during the first weeks of treatment
- Allergic reactions (hypersensitivity), which can include skin rash (of varying severity), itching, breathlessness and, very rarely, fever or rapid swelling of the skin.

Uncommon side effects – appear in 1-10 in 1,000 users:

- Depression – usually transient and may occur during the first weeks of treatment
- Constriction of the lower airways (bronchospasm)
- Vomiting and abdominal pain under the ribs
- Sweating – usually transient and occurs during the first weeks of treatment
- Muscle cramps.

Rare side effects – appear in 1-10 in 10,000 users:

- Slowing of heart rate, which can be felt as a slow pulse (bradycardia).

Very rare side effects – appear in less than one in 10,000 users:

- Disturbances to the electric impulses (signs) that control the heartbeat (heart block)
 - Inflammation of the liver (hepatitis), which usually returns to normal once you have stopped taking the medicine
 - Hepatocellular jaundice (the skin and the whites of the eyes turn yellow), cholestatic jaundice (the symptoms include fatigue and nausea followed by itching, dark urine and jaundice, and may include skin rash or fever) and hepatic necrosis (damaged liver tissue). These symptoms usually return to normal once you have stopped treatment with the medicine.
 - Aggravated symptoms of Raynaud's syndrome (cold fingers due to decreased blood circulation)
 - Swollen ankles – this effect is usually transient and occurs during the first weeks of treatment
 - Muscle inflammation and weakness caused by taking the medicine (toxic myopathy)
 - Trembling when Trandate is used to treat hypertension in pregnant women
 - Eye irritation
- Side effects of unknown frequency (effects whose frequency has not been determined yet):**
- Nipple pain
 - Periodic decrease in blood flow to the nipples, which may cause the nipples to become numb, pale and painful (Raynaud's phenomenon)

If a side effect occurs, if one of the side effects worsens or if you are suffering from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting side effects:

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

In addition, you can report to Padagis via the following address: Padagis.co.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a closed place out of reach and sight of children and/or infants, in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use this medicine after the expiry date (exp. date) that appears on the package and the bottle label. The expiry date refers to the last day of that month.
- Store below 30°C.
- Medicines should not be disposed of via wastewater or household waste. Ask the pharmacist how to dispose of medicines that you no longer need. These measures will help to protect the environment.

6. ADDITIONAL INFORMATION

In addition to the active ingredient, the medicine also contains: Microcrystalline cellulose, Lactose anhydrous, Magnesium stearate, Opadry Orange 02A230001 [Hypromellose 5cP, Titanium dioxide, Sunset Yellow FCF (E110), Sodium benzoate].

What the medicine looks like and the contents of the package: Trandate 100 mg tablets are supplied in a plastic bottle containing 50 round, biconvex, orange-colored, film-coated tablets, marked TT01 on one side.

Trandate 200 mg tablets are supplied in a plastic bottle containing 50 round, biconvex, orange-colored, film-coated tablets, marked TT02 on one side.

Registration holder: Padagis Israel Agencies Ltd., 1 Rakefet St., Shoham.

Manufacturer: Aspen Bad Oldesloe GmbH, Bad Oldesloe, Germany.

Revised in May 2023 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Trandate tablets 100 mg: 2086.27785

Trandate tablets 200 mg: 2084.27786