

The dispensing of this medicine requires a physician's prescription

Read this package insert carefully in its entirety before using this medicine

The format of this leaflet was determined by the Ministry of Health  
and its content was checked and approved in May 2013

# TRANDATE™ TABLETS

## 100 mg

# TRANDATE™ TABLETS

## 200 mg

### Composition:

#### Active ingredient and quantity:

Each tablet contains:  
Labetalol Hydrochloride 100 mg

Each tablet contains:  
Labetalol Hydrochloride 200 mg

#### Inactive ingredients:

Each tablet also contains lactose 14.625 mg                      Each tablet also contains lactose 29.25 mg  
Lactose Anhydrous, Microcrystalline Cellulose, Magnesium Stearate, Hypromellose 5cP, Opaspray Orange  
M-1-3499D (Industrial Methylated Spirit, Sodium Benzoate, Titanium Dioxide, Sunset Yellow FCF, Hypromellose  
5cP).

#### Therapeutic group:

Combined beta and alpha receptor antagonist.

#### Therapeutic activity:

A product from the beta receptor blockers group for the treatment of all grades of hypertension.

#### When should the medicine not be used?

Do not use this medicine if you have a known sensitivity to any of its ingredients.  
Do not use this medicine if you suffer from second or third degree heart block, cardiogenic shock and other  
conditions accompanied by severe and prolonged hypotension or bradycardia.  
Do not use this medicine if you suffer from asthma or from airways obstruction.

#### Do not take this medicine without consulting a physician before starting treatment:

If you are pregnant or breastfeeding.  
If you suffer or have suffered in the past from impaired function of: the respiratory system, the heart and/or  
vascular system, the liver, the thyroid.  
If you suffer or have suffered in the past from diabetes, from pheochromocytoma.

#### How will this medicine affect your daily life?

Use of this medicine may cause dizziness and fatigue and therefore caution should be exercised when driving a  
car, operating dangerous machinery and engaging in any activity which requires alertness.

#### Warnings:

If you are sensitive to any type of food or medicine, inform your physician before taking this medicine.  
During treatment with this medicine, blood pressure measurements, liver function and heart tests should be  
performed.  
Inform your physician that you are taking **Trandate Tablets** if you are scheduled for any type of surgery (including  
eye surgery - cataract, dental surgery).  
Due to the drop in blood pressure, caution is required when standing for a prolonged period, during physical  
activity, when drinking alcohol, and in hot weather.  
This medicine may cause sensitivity to cold weather, make sure that you dress warmly and avoid prolonged  
exposure to the cold.  
This medicine may decrease or prevent chest pain during physical exertion, therefore, consult your physician  
regarding the level of physical activity you are allowed.  
A drop in blood pressure followed by fainting may occur, especially when standing up from a sitting or lying  
position. Getting up slowly may help. When rising from a lying position, sit on the edge of the bed with your legs  
dangling for 1-2 minutes. Then stand up slowly. If this problem perseveres or worsens, refer to your physician.  
Patients with ischemic heart disease should discontinue treatment with the medicine gradually. Do not discontinue  
treatment with the medicine abruptly, refer to your physician.  
As with other beta receptor blockers, the medicine may mask the symptoms of low blood sugar level in diabetic  
patients and of high levels of thyroid hormones.  
The tablets contain lactose.

#### Drug interactions:

If you are taking another medicine, or if you have just finished treatment with another medicine, including non-  
prescription medicines, inform the attending physician, in order to prevent hazards or lack of efficacy arising  
from drug interactions, especially for medicines belonging to the following groups: medicines for treatment of  
depression of the monoamine oxidase inhibitor type (MAO-A), tricyclics; anesthetics (e.g. halothane); cimetidine  
for treatment of stomach ulcer; hydralazine for the treatment of hypertension; calcium channel blockers (e.g.:  
verapamil, diltiazem, nifedipine); medicines for regulating heart rate (e.g. digoxin); prostaglandin synthesis  
inhibitors (NSAIDs); adrenalin; radioactive isotopes of metaiodobenzylguanidine; alpha blockers for the treatment  
of hypertension.

#### Side effects:

In addition to the desired effect of the medicine, while using this medicine adverse reactions that should be  
reported to your physician may occur, such as: headache, dizziness, depressed mood, blurred vision, eye  
irritation, nasal congestion, sweating, tiredness, state of severe weakness and lack of energy, swelling of ankles,  
tingling sensation in scalp.  
Nausea and vomiting, sleep disorders, epigastric pains, raised liver function tests, muscle cramps, in men -  
erectile and ejaculation problems.

#### Side effects that require special attention:

If you experience the following side effects - refer to the physician immediately:  
Hypersensitivity manifested by skin rash, itching, shortness of breath and very rarely fever or swelling of the  
tissue under the skin.  
Congestive heart failure, bradycardia (rare), heart block (very rare), hypotension when standing.  
Exacerbation of the symptoms of Raynaud's syndrome (rare), e.g.: pallor and feeling pain in the fingers and  
toes.  
Narrowing of airways.  
Tremor (rare) - when treating hypertension in pregnant women.  
Dry eyes (rare).  
Difficulty in passing urine, urinary retention (rare).  
Hepatitis, jaundice, hepatic necrosis (rare) - these signs are reversible after treatment with the medicine is  
discontinued.  
In the event that you experience side effects not mentioned in this leaflet, or if there is a change in your general  
health, consult your physician immediately.

#### Reporting side effects:

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug  
Treatment" found on the Ministry of Health homepage ([www.health.gov.il](http://www.health.gov.il)) that directs you to the online form  
for reporting side effects, or by entering the link:  
<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>  
In addition, you can report to Perrigo via the following address: [www.perrigo-pharma.co.il](http://www.perrigo-pharma.co.il)

#### Dosage:

Dosage is according to physician's instructions only.  
Do not exceed the recommended dosage.  
This medicine is not intended for children.  
This medicine is to be taken at specific time intervals as determined by the attending physician.  
If you forgot to take this medicine at the specified time, take the dose as soon as you remember; but never take  
two doses together! Skip the dose if less than 4 hours are left until the next dose.  
Make sure to keep a low sodium diet during the period of treatment.

#### Directions for use:

Do not chew! Swallow the medicine with a small amount of water.  
Do not halve or crush the tablet.  
Take the medicine with a meal.

#### Avoid poisoning!

This medicine, and all other medicines, must be stored in a safe place out of the reach of children and/or infants,  
to avoid poisoning. If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed  
immediately to a hospital emergency room and bring the package of the medicine with you.  
Do not induce vomiting unless explicitly instructed to do so by a physician!  
This medicine has been prescribed for the treatment of your ailment, in another patient it may cause harm.  
Do not give this medicine to your relatives, neighbors or acquaintances.  
Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses  
if you need them.

#### Storage:

Store below 30°C.  
After first opening can be used for 50 days.  
Even if kept in their original container and stored as recommended, medicines may be kept for a limited period  
only. Please note the expiry date of the medicine! In case of doubt, consult the pharmacist who dispensed the  
medicine to you.  
Do not store different medications in the same package.

#### License numbers:

Trandate tablets 100 mg: 2086.27785  
Trandate tablets 200 mg: 2084.27786

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

Registration holder: Perrigo Israel Agencies Ltd., 29 Lehi St., Bnei-Brak 51200.