

Package leaflet: Information for the patient
Trandate 100 mg film-coated Tablets and Trandate 200 mg 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. 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.
- In this leaflet Trandate 100 mg film-coated Tablets and Trandate 200 mg film-coated Tablets will be called Trandate.

In this leaflet:

1. What Trandate is and what it is used for
2. What you need to know before you take Trandate
3. How to take Trandate
4. Possible side effects
5. How to store Trandate
6. Contents of the pack and further information

1. What Trandate is and what it is used for

Trandate belongs to a group of medicines called beta blockers.

Trandate works by causing the heart to beat more slowly and with less force. It also widens the arteries in the body. This helps to lower the pressure of the blood as it travels around the body. The result is a lower blood pressure and the prevention of angina (chest pain).

Trandate are used to treat:

- High blood pressure
- High blood pressure in pregnant women
- Angina (chest pains) with and without high blood pressure
- Long term management of high blood pressure after a heart attack

High blood pressure often causes no obvious symptoms but if it is not treated it can damage blood vessels in the long-term. This can lead to heart attacks, kidney failure, stroke or blindness. This is why it is important not to stop taking this medicine without talking to your doctor.

2. What you need to know before you take Trandate

Do not take Trandate :

- if you are allergic to labetalol hydrochloride or any other ingredients of this medicine (listed in section 6)
- if you suffer from wheezing, obstructive airways disease or asthma – taking Trandate can make your breathing worse
- if you have a problem that is common in the elderly, related to poor control of the working of your heart (sick sinus syndrome)
- if you have a heart defect that leads to a decreased function of the heart (heart block)
- if your heart cannot maintain adequate circulation of blood (cardiogenic shock)
- if you have weak heart or a very slow heart beat (less than 45 or 50 beats per minute)
- if you suffer from Prinzmetal's angina (chest pains) when at rest
- if you have a tumour near your kidneys (phaeochromocytoma)
- if you have increased acid levels in the blood (metabolic acidosis)

- if you have low blood pressure (hypotension)
- if you have heart failure that is out of control or not responding to treatment with digitalis
- if you have very bad circulation, especially in your hands and feet

If any of the above applies to you talk to your doctor or pharmacist.

Warnings and Precautions:

Talk to your doctor or pharmacist before taking Trandate :

- if you are about to receive an anaesthetic: as Trandate may mask the effects of a sudden loss of blood
- if you suffer or have suffered from any serious allergic reactions
- if you have ever suffered from a skin condition called psoriasis
- if you have kidney or liver problems
- if you are receiving a procedure called MIBG scintigraphy (often used to detect certain tumours)
- You are elderly (65 years and over)
- if you are scheduled for cataract surgery as labetalol may affect your pupils during this procedure. Please tell your eye surgeon before your surgery about your treatment with this medicine. You do not need to stop treatment with this medicine unless your surgeon advises otherwise
- 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)
- if your heart rate slows to less than 50 -55 beats per minute while at rest (bradycardia)
- if you have a reduced blood supply to the heart muscle (ischaemic heart disease)
- if you have an irregular heart beat (first degree heart block)
- if you have poor circulation e.g. fingers and toes go numb and pale (Reynaud's syndrome) or you sometimes limp (intermittent claudication).

Other medicines and Trandate Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including:

- Barbiturates such as phenobarbitone (used as a sedative or in epilepsy) as this may increase the effect of Trandate.
- Use of Xamoterol as this may counteract or interfere with the effects of labetalol.
- Blood pressure lowering medicines such as verapamil and diltiazem (calcium channel blocking medicines) should not be used with Trandate as this can result in a low heart rate and heart failure.
- Use of medicines to control heart rhythm such as disopyramide, quinidine and amiodarone
- Use of over-the-counter medicines that are used to relieve nasal congestion (decongestants) as they interact with labetalol
- Drugs that affect the nervous system (sympathomimetic agents)
- Use of Trandate with the blood pressure lowering medicine clonidine is not recommended as this combination might lead to high blood pressure
- Use of antimalarials such as halofantrine, mefloquine or quinine as this may cause slow heart rate (bradycardia).
- Anaesthetics such as cyclopropane and trichloroethylene as these should not be used with Trandate.
- Hydralazine (a medicine used to reduce blood pressure) as this may result in increased effects of Trandate.
- The use of labetalol interferes with laboratory tests for catecholamines.
- Tropisetron may increase the risk of abnormal heart rate (ventricular arrhythmia).
- Medicines to treat your heart or blood pressure such as digitalis, amiodarone, nifedipine, enalapril, lisinopril, ramipril, losartan, valsartan, bendroflumethiazide, chlorthalidone, indapamide, terazosin or doxazosin
- Medicines to treat depression such as monoamine oxidase inhibitors or tricyclic antidepressants
- Medicines for anxiety and sedation such as temazepam, diazepam, lorazepam
- Non-steroidal anti-inflammatory drugs (NSAIDs) and corticosteroids such as ibuprofen, naproxen, betamethasone used to treat inflammatory conditions such as rheumatoid arthritis or asthma
- Cimetidine used to treat stomach ulcers

- Insulin or oral anti-diabetic drugs
- Treatment for mental disturbances such as chlorpromazine
- Medicines to treat acute migraine such as ergotamine
- Alprostadil to treat impotence
- Aldesleukin for the treatment of secondary cancer of the kidney
- Moxyslyte to treat Raynauds disease, a condition that affects the blood circulation to the fingers and toes causing them to suddenly become white, numb and cold
- Hormones such as oestrogen and progesterone used as contraceptives or hormone replacement therapy
- Any other medicine, including medicines obtained without a prescription.

Taking Trandate Tablets at the same time as the drugs mentioned for treating your heart or blood pressure can lead to a severe drop in blood pressure, reduced heart rate, heart failure or heart block. It is important to tell your doctor if you are taking these or any of the other drugs listed above.

Trandate with food, drink and alcohol

Always take your tablets with food. As a safety precaution it is recommended to avoid alcohol.

Pregnancy and breast-feeding

Trandate should only be used during the first 3 months of pregnancy if it is absolutely necessary. Therefore tell your doctor if you are pregnant or trying to become pregnant.

Trandate is not recommended whilst breast feeding.

Nipple pain and Raynaud's phenomenon of the nipple have been reported (see section 4).

Driving and using machines

You may feel dizzy or tired when taking Trandate. If this happens to you, do not drive or operate machinery.

Trandate contains lactose monohydrate

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

Trandate contains methyl hydroxybenzoate (E218) and propyl hydroxybenzoate (E216)

May cause allergic reactions (possibly delayed).

Trandate contains sunset yellow (E110)

May cause allergic reactions.

Trandate contains sodium benzoate (E211)

This medicine contains 0.15mg of sodium benzoate in each 100mg film-coated tablet and 0.3mg in each 200mg film-coated tablet.

Trandate contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'

3. How to take Trandate tablets

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

Remember: Your tablets should be swallowed whole and should be taken with food.

Adults:

High blood pressure, with or without angina

- Treatment should start with 100mg twice a day.
- Every two weeks your doctor may increase the dose by 100 mg twice a day until your blood pressure is controlled.
- In more serious cases of high blood pressure your doctor may want to increase the dose up to 2400 mg a day. In this case you will need to take your medicine 3 or 4 times a day.

High blood pressure during pregnancy

- The usual starting dose is 100 mg twice a day.
- Your doctor may increase your dose every week by 100 mg twice a day.
- As pregnancy continues your dose may need to be increased to between 100 mg and 400 mg three times a day.
- A total daily dose of 2400 mg should not be exceeded.

Elderly:

- In elderly patients, reduced daily doses compared to adults.
- Use of the 100 mg dosage in elderly is subject to the prescriber's evaluation.

Use in children:

Trandate is not recommended for children.

If you take more Trandate than you should

Do not take more Trandate than you should.

If you accidentally take too many tablets, contact your doctor or contact nearest hospital emergency department. Remember to take this leaflet or any remaining tablets with you if possible.

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 Trandate

Do not take a double dose to make up for a forgotten dose. Simply take the next dose as planned.

If you stop taking Trandate

Do not stop taking Trandate suddenly. Continue taking them until your doctor tells you to stop. He or she will gradually reduce the dose over a few weeks if necessary.

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

4. Possible side effects

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

Remember:

Stop using Trandate and seek immediate medical help if you have an allergic reaction. This includes any of the following symptoms:

- **Difficulties in breathing**
- **Swelling of your eyelids, face or lips**
- **Rash or itching.**

Most of the side effects related to Trandate will wear-off after the first few weeks.

These include:

Not Known (frequency cannot be estimated from available data)

- Headaches, tiredness or dizziness
- Depression or exhaustion (lethargy)
- Tingling of the scalp, or a blocked nose
- Swollen ankles or sweating
- Difficulty passing urine or not being able to pass urine

- Not being able to ejaculate
- Stomach pain, feeling sick or being sick
- The shakes after taking Trandate when pregnant
- Dizziness when standing up (when taken at very high doses)
- Low blood pressure (hypotension)
- Poor circulation in the hands, cold or blue extremities, numbness or tingling of the extremities
- Increase of existing leg pain on walking
- Mental disturbances such as delusions and altered thought patterns, hallucinations or confusion
- Sleep disturbances including nightmares
- Diarrhoea
- Wheezing or shortness of breath (in patients with asthma)
- the symptoms of an overactive thyroid (increased heart rate) or low blood sugar (as seen in blood test results) may be hidden
- High blood potassium levels (hyperkalaemia) especially if you have reduced kidney function.
- Hair loss, this may grow back after stopping treatment
- Worsening of psoriasis
- Heart failure causing shortness of breath with swelling of the feet and ankles
- Poor blood circulation leading to cold or blue extremities with numbness or tingling in your fingers and toes
- Nipple pain
- Intermittent decrease in blood flow to your nipples, which may cause your nipples to go numb, pale, and painful (Raynaud's phenomenon)

If any of these side effects occur, speak to your doctor immediately.

Not Known (frequency cannot be estimated from available data)

- Problems with the immune system (e.g. systemic lupus erythematosus) causing shortness of breath, joint pain, or a rash on the cheeks and arms that worsen with sun exposure
- Thrombocytopenia causing bleeding because your blood does not clot as it should
- Drug fever making you feel hot and flu-like
- Muscle disease (toxic myopathy) causing weakness and wasting of the muscles in the arms and legs
- Flat topped bumps on your skin that join up into scaly patches (lichenoid rash)
- Blurred vision or dry eyes
- Cramps
- Liver problems or jaundice causing discomfort and tenderness in the upper abdomen, yellowing of the skin and whites of the eyes
- Slowing of the heart and heart block (where the heart signals are delayed causing your heartbeat to slow to 20 -40 beats per minute)
- Cough or breathing problems that may indicate inflammation of the lungs (interstitial lung disease)

Rare side effects on your baby

If you are being treated for high blood pressure during pregnancy your baby may suffer the following effects for a few days after birth:

- Low blood pressure
- Slow heart beat
- Shallow or slow breathing
- Low blood sugar
- Feeling cold

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 HPRA Pharmacovigilance, Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Trandate tablets

Keep this medicine out of the sight and reach of children.

Do not use Trandate after the expiry date which is shown on the carton label, blister foil and container label after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and further information

What Trandate contains

The active ingredient is labetalol hydrochloride.

The tablets contain either 100 mg or 200 mg of the active ingredient.

The other ingredients are: In the tablet core:

lactose monohydrate, magnesium stearate (E572), starch maize. In the film coating: hypromellose (E464), sodium benzoate (E211), titanium dioxide (E171), sunset yellow (E110), methyl hydroxybenzoate (E218), propyl hydroxybenzoate (E216), industrial methylated spirit and purified water.

What Trandate looks like and the contents of the pack

The tablets are orange with either 'Trandate 100' or 'Trandate 200' written on one side. They come in packs containing 56 or 250 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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If this leaflet is difficult to see or read or you would like it in a different format, please contact RPH Pharmaceuticals AB, Box 603, 101 32 Stockholm, Sweden.