



Read all of this leaflet carefully before you start taking this medicine.

- 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 symptoms are the same as yours.
- In this leaflet Trandate 50mg film-coated Tablets, Trandate 100mg film-coated Tablets, Trandate 200mg film-coated Tablets and Trandate 400mg film-coated Tablets will be called Trandate.

In this leaflet:

1. What Trandate is for
2. Before you take Trandate
3. How to take Trandate
4. Possible side effects
5. How to store Trandate
6. Further information

1. What Trandate is 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) if you already have high blood pressure

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. Before you take Trandate

Do not take Trandate if:

- You are allergic to labetalol hydrochloride
- You are allergic to any of the other ingredients of Trandate (see section 6)
- You suffer from wheezing, obstructive airways disease or asthma – taking Trandate can make your breathing worse
- You have a problem that is common in the elderly, related to poor control of the working of your heart (sick sinus syndrome)
- You have a heart defect that leads to a decreased function of the heart (heart block)
- Your heart cannot maintain adequate circulation of blood (cardiogenic shock)
- You have weak heart or a very slow heart beat (less than 45 or 50 beats per minute)
- You have low blood pressure (hypotension)
- You have heart failure that is out of control or not responding to treatment with digitalis

- You suffer from angina (chest pains) when at rest
- You have very bad circulation
- You have liver disease or your liver was affected when taking labetalol in the past
- You have a tumour near your kidneys (phaeochromocytoma)
- You have increased acid levels in the blood (metabolic acidosis)

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

Check with your doctor before taking Trandate if:

- You are about to receive an anaesthetic: as Trandate may mask the effects of a sudden loss of blood
- You suffer or have suffered from any serious allergic reactions
- You have ever suffered from a skin condition called psoriasis
- You are receiving a procedure called MIBG scintigraphy (often used to detect certain tumours)
- 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.

Tell your doctor if you are taking any of the following medicines

- Medicines used to treat your heart or blood pressure such as digitalis, amiodarone, nifedipine, enalapril, lisinopril, ramipril, losartan, valsartan,

- bedroflumethiazide, chlorthalidone, indapamide, terazosin, 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), corticosteroids or other medicines such as ibuprofen, naproxen, betamethasone used to treat pain or 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
- Antimalarial medicines such as mefloquine or quinine
- Medicines used to treat acute migraine such as ergotamine
- Alprostadil to treat impotence
- Moxisylyte to treat Raynaud's disease a condition that affect the blood circulation to the fingers and toes causing them to suddenly become white, numb and cold
- Aldesleukin for the treatment of secondary cancer of the kidney
- Hormones such as oestrogen and progesterone used as contraceptives or for hormone replacement therapy
- Medicines for stimulating the heart e.g. adrenaline
- Any other medicine, including medicines obtained without a prescription.

Taking Trandate 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.

The results of blood or urine tests may be affected by taking Trandate. If you need to have a blood or urine test, tell your doctor that you have been given Trandate tablet.

Taking Trandate with food and drink

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.

Driving and using machines

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

Warnings about the ingredients in Trandate

Trandate contains sodium benzoate which is a mild irritant to the eyes, nose and mucous membranes. It may increase the risk of jaundice in new born babies. If you think this medicine has upset you (or your baby) in any way, please tell your doctor as soon as possible.

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

3. How to take Trandate tablets

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

IMPORTANT:

Your doctor will choose the dose that is right for you. Your dose will be shown clearly on the label that your pharmacist puts on your medicine. If it does not, or you are not sure, ask your doctor or pharmacist.

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

Adults:

High blood pressure, with or without angina

- The starting dose is usually 100 mg 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:

- The starting dose is 50 mg twice a day.

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 take too many tablets tell your doctor immediately or contact your nearest hospital emergency department. You should take your tablets with you if possible.

If you forget to take Trandate

Do not take a double dose to make up for a missed 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 about 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.

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:

- 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 or to ejaculate
- Stomach pain, feeling sick or being sick

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

- 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 nosebleeds or bleeding in the mouth or bruising 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 heart beat to slow to 20 - 40 beats per minute)

- Cough or breathing problems that may indicate inflammation of the lungs (interstitial lung disease)
 - Poor blood circulation leading to nipple pain, cold or blue extremities with numbness or tingling in your fingers and toes
- Other side effects that may occur include:**
- The shakes after taking Trandate when pregnant
 - Dizziness when standing up (when taken at very high doses)
 - Low blood pressure (hypotension) causing dizziness and possibly fainting
 - 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. This may cause your heart beat to become irregular or may be without symptoms and only show on blood test results
 - 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

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 Yellow Card Scheme Website: 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 Trandate

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.

No special storage conditions are necessary. Medicines should not be disposed of via wastewater or household waste. Return any

medicine you no longer need to your pharmacist.

6. Further Information

What Trandate contains

The active ingredient is labetalol hydrochloride. The tablets contain either 50mg, 100mg, 200mg or 400mg 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

The tablets are orange with either 'Trandate 50', 'Trandate 100', 'Trandate 200' or 'Trandate 400' written on one side. Trandate 50mg tablets come in packs containing 56 tablets. Trandate 100mg, Trandate 200mg and Trandate 400mg tablets come in packs containing 56 or 250 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

RPH Pharmaceuticals AB, Lagervägen 7, 136 50 Haninge, Sweden.

Manufacturer

Recipharm Uppsala AB, Björkgatan 30, SE-751 82, Uppsala, Sweden.

This leaflet was last revised in November 2019.

If this leaflet is difficult to see or read or you would like it in a different format, please contact RPH Pharmaceuticals AB, Lagervägen 7, 136 50 Haninge, Sweden.