

**Package leaflet: Information for the patient**  
**Trandate 5mg/ml solution for injection**  
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.
- 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

**What is in this leaflet:**

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

**1. What Trandate injection is for**

In this leaflet Trandate 5 mg/ml Solution for Injection will be called Trandate injection.

Trandate injection belongs to a group of medicines called beta blockers.

Trandate injection 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 rapid lowering of a person's blood pressure. Trandate injection is given in hospital and can be used to:

- Lower very high blood pressure, especially in pregnant women
- Keep your blood pressure down during an operation
- Lower high blood pressure after a heart attack.

It is very important that the doctor treats your high blood pressure, because left untreated it can cause damage to your blood vessels in the long-term. This could lead to heart attacks, kidney failure, stroke or blindness.

**2. What you need to know before you are given Trandate injection**

**Do not use Trandate injection :**

- if you are allergic to labetalol hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- if your heart cannot maintain adequate circulation of blood (cardiogenic shock)
- if you have heart failure that is out of control or not responding to treatment with digitalis
- 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 you suffer from Prinzmetal's angina (chest pains) when at rest
- if you suffer from wheezing, obstructive airways disease or asthma – taking Trandate can make your breathing worse
- if you have a tumour near your kidneys (phaeochromocytoma)
- if you have increased acid levels in the blood (metabolic acidosis)
- if you have a weak heart or a very slow heart beat (less than 45 or 50 beats per minute)
- if you have low blood pressure (hypotension)
- if you have very bad circulation, especially in your hands and feet.

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

### **Warnings and Precautions:**

Talk to your doctor or pharmacist before using Trandate Injection :

- 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 in the past
- if you have ever suffered from a skin condition called psoriasis
- if you have kidney or liver problems
- 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).

### **Children**

This medicine is not suitable for children.

### **Other medicines and Trandate Injection**

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
- 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
- Moxisylyte 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 injection 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.

#### **Taking with alcohol**

As a safety precaution it is recommended to avoid alcohol.

#### **Pregnancy and breast-feeding**

Trandate injection 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 injection is not recommended whilst breast feeding.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before being given this medicine.

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 injection. If this happens to you, do not drive or operate machinery.

#### **Sodium content**

This medicine contains less than 1mmol sodium (23mg) per 20ml vial, that is to say essentially 'sodium free'.

### **3. How you will be given Trandate injection**

Trandate injection is usually only given to patients in hospital by a doctor or anaesthetist. It may be given as an injection into a vein, or by a slow drip depending on how quickly your blood pressure needs to be reduced.

#### **IMPORTANT:**

**Your doctor will decide how the Trandate injection will be given to you and the correct dose for you.**

Remember: You should only be given this drug if you are lying down.

You should avoid sitting upright for three hours after being given Trandate injection as you may feel very dizzy and lightheaded.

While you are having Trandate injection your doctor may check your heart rate, blood pressure and breathing to check your medicine is working properly.

**Adults:**

**Injection into a vein (to reduce blood pressure very quickly)**

- A dose of 50 mg of Trandate injection will be given into your vein over a period of one minute
- If necessary this dose can be repeated every five minutes up to three times until your blood pressure has been lowered
- The total dose should not exceed 200 mg.

**Slow drip into a vein (to reduce blood pressure more slowly)**

- A solution containing 1 mg/ml Trandate injection will be made up by the doctor or nurse
- The solution will then be given to you via a drip into your vein
- The amount of the solution you will be given will depend on why your blood pressure needs to be lowered:

1. To lower high blood pressure in pregnancy

- 20 mg of Trandate injection will be given over one hour
- The dose may then be doubled every 30minutes until your blood pressure has been reduced or the dose has reached 160 mg per hour
- Your doctor may occasionally need to use a higher dose.

2. To lower high blood pressure after a heart attack

- 15 mg of Trandate injection will be given over one hour
- The dose may then be gradually increased up to a maximum of 120 mg per hour if needed.

3. To lower high blood pressure for other reasons

- 2 mg of Trandate injection will be given per minute
- When your blood pressure is low enough, the doctor will stop your drip
- Your doctor may change the rate at which the drip goes in depending on how well you are responding to the medicine
- The total dose given is usually between 50 mg and 200 mg, but occasionally higher doses may be needed.

**To lower blood pressure during an operation**

- Whilst you are under anaesthetic, 10-20 mg Trandate injection (depending on your age and health) will be injected into your vein
- If after 5 minutes your blood pressure has not been reduced, a dose of 5-10 mg can be given every 5 minutes until your blood pressure is low enough.

**Maintaining your blood pressure**

- After you have had Trandate injection your doctor may suggest you take Trandate tablets to keep your blood pressure low
- If this applies to you, your doctor or pharmacist will tell you exactly how many tablets to take, and when to take them.

**People with liver or kidney problems:**

If you have problems with your liver or kidneys, your doctor may give you a lower dose of Trandate injection.

**The elderly (65 years and over):**

Your doctor may start you on a lower dose than the usual adult dose to make sure that the medicine is working properly.

**Use in children:**

Trandate injection is not recommended for use in children.

**If you are given more Trandate injection than you should**

If you think you may have been given too much Trandate injection, tell your doctor immediately.

**If you stop taking Trandate Injection**

Your doctor will decide to stop giving you Trandate injection.

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

**4. Possible side effects**

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

**Remember:**

**You should avoid sitting upright for three hours after being given Trandate injection as you may feel very dizzy and lightheaded. Stop using Trandate injection 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 injection 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 HPRC Pharmacovigilance, Website: [www.hpra.ie](http://www.hpra.ie)

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

**5. How to store Trandate injection**

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

Do not use Trandate injection after the expiry date which is stated on the carton and the ampoule label after EXP. The expiry date refers to the last day of that month.

Do not store above 30° C.

Keep the ampoules in the original packaging in order to protect from light.

For single use only. The product should not be used if there are any signs of discoloration or presence of particles in the solution. Once opened use immediately and discard any unused solution.

Medicines should not be disposed of via wastewater or household waste. Your doctor or nurse will make sure your medicine is correctly stored and disposed of.

## **6. Contents of the pack and further information**

### **What Trandate injection contains**

- The active ingredient is labetalol hydrochloride. Each ml of liquid contains 5 mg of the active ingredient.
- The other ingredients are dilute hydrochloric acid (E507) and sodium hydroxide (E524) for pH adjustment and water for injection.

### **What Trandate injection looks like**

Trandate 5 mg/ml Solution for Injection is a clear colourless solution.

Trandate injection comes in 20 ml glass ampoules, with 5 ampoules in each pack.

### **Marketing Authorisation Holder**

RPH Pharmaceuticals AB, Box 603  
101 32 Stockholm, Sweden.

### **Manufacturer**

Mitim S.r.l.  
Via G.B. Cacciamali, 34/36/38  
25125 Brescia  
Italy

**This leaflet was last revised in 02/2022.**

**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.**

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**Technical Leaflet intended for healthcare professionals only**

**TRANDATE 5 MG/ML SOLUTION FOR INJECTION GENERAL INFORMATION**

Trandate 5 mg/ml Solution for Injection is for single use only. Once opened, the product should be used immediately. Discard any unused material.

**THERAPEUTIC INDICATIONS**

Trandate Injection is indicated for the treatment of:

1. Severe hypertension, including severe hypertension of pregnancy, when rapid control of blood pressure is essential.
2. Anaesthesia when a hypotensive technique is indicated.
3. Hypotensive episodes following acute myocardial infarction.

**POSODOGY AND METHOD OF ADMINISTRATION**

**Adults:**

Trandate Injection is intended for intravenous use in hospitalised patients. The plasma concentrations achieved after intravenous dose of Trandate in severe hypertension are substantially greater than those following oral administration of the drug and provide a greater degree of blockade of alpha-adrenoceptors necessary to control the more severe disease. Patients should, therefore, always receive the drug whilst in the supine or left lateral position. Raising the patient into the upright position, within three hours of intravenous Trandate administration, should be avoided since excessive postural hypotension may occur.

**Bolus injection**

If it is essential to reduce blood pressure quickly, as for example, in hypertensive encephalopathy, a dose of 50mg of Trandate should be given by intravenous injection over a period of at least one minute. If necessary, doses of 50mg may be repeated at five minute intervals until a satisfactory response occurs. The total dose should not exceed 200mg. After bolus injection, the maximum effect usually occurs within five minutes and the effective duration of action is usually about six hours but may be as long as eighteen hours.

**Intravenous infusion**

An alternative method of administering Trandate is intravenous infusion of a solution made by diluting the contents of two ampoules (200mg) to 200ml with Sodium Chloride and Dextrose Injection BP or 5% Dextrose Intravenous Infusion BP. The resultant infusion solution contains 1mg/ml of Trandate. It should be administered using a paediatric giving set fitted with a 50ml graduated burette to facilitate dosage.

***In the hypertension of pregnancy:*** The infusion can be started at the rate of 20mg per hour and this dose may be doubled every thirty minutes until a satisfactory reduction in blood pressure has been obtained or a dosage of 160mg per hour is reached.

Occasionally, higher doses may be necessary.

***In hypertensive episodes following acute myocardial infarction:*** The infusion should be commenced at 15mg per hour and gradually increased to a maximum of 120mg per hour depending on the control of blood pressure.

***In hypertension due to other causes:*** The rate of infusion of Trandate should be about 2mg (2ml of infusion solution) per minute, until a satisfactory response is obtained; the infusion should then be

stopped. The effective dose is usually in the range of 50-200mg depending on the severity of the hypertension. For most patients it is unnecessary to administer more than 200mg but larger doses may be required especially in patients with phaeochromocytoma. The rate of infusion may be adjusted according to the response, at the discretion of the physician. The blood pressure and pulse rate should be monitored throughout the infusion.

It is desirable to monitor the heart rate after injection and during infusion. In most patients, there is a small decrease in the heart rate; severe bradycardia is unusual but may be controlled by injecting atropine 1-2mg intravenously. Respiratory function should be observed particularly in patients with any known impairment.

Once the blood pressure has been adequately reduced, maintenance therapy with Trandate tablets should be instituted with a starting dose of one 100mg tablet twice daily (see Trandate tablets SmPC for further details). Trandate Injection has been administered to patients with uncontrolled hypertension already receiving other hypotensive agents, including beta-blocking drugs, without adverse effects.

***In hypotensive anaesthesia:*** Induction should be with standard agents (e.g. sodium thiopentone) and anaesthesia maintained with nitrous oxide and oxygen with or without halothane. The recommended starting dose of Trandate Injection is 10-20mg intravenously depending on the age and condition of the patient. Patients for whom halothane is contra-indicated usually require a higher initial dose of Trandate (25-30mg). If satisfactory hypotension is not achieved after five minutes, increments of 5-10mg should be given until the desired level of blood pressure is attained.

Halothane and Trandate act synergistically therefore the halothane concentration should not exceed 1-1.5% as profound falls in blood pressure may be precipitated.

Following Trandate Injection the blood pressure can be quickly and easily adjusted by altering the halothane concentration and/or adjusting table tilt. The mean duration of hypotension following 20-25mg of Trandate is fifty minutes.

Hypotension induced by Trandate Injection is readily reversed by atropine 0.6mg and discontinuation of halothane.

Tubocurarine and pancuronium may be used when assisted or controlled ventilation is required. Intermittent Positive Pressure Ventilation (IPPV) may further increase the hypotension resulting from Trandate Injection and/or halothane.

**Children:**

Safety and efficacy have not been established.

**STORAGE AND DISPOSAL OF TRANDATE 5 MG/ML SOLUTION FOR INJECTION**

Do not store above 30°C.

For single use only. Discard any remaining contents immediately after use.

**Shelf life:** Unopened: 2 years

Once opened, the product should be used immediately.