

NEW ZEALAND CONSUMER MEDICINE INFORMATION

TRANDATE

Labetalol solution for injection 5 mg/mL



What is in this leaflet

Please read this leaflet carefully before you are given TRANDATE.

This leaflet answers some common questions about TRANDATE.

It does not contain all the available information. It does not take the place of talking to your doctor, nurse or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of giving you TRANDATE against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor, nurse or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What TRANDATE is used for

TRANDATE is used to

Rapidly lower very high blood pressure (called severe hypertension)

Lower blood pressure during an operation requiring certain types of anaesthetics (medicines that put you to sleep during an operation)
Quickly lower high blood pressure, if necessary, after a heart attack

TRANDATE contains the active ingredient labetalol. It belongs to a group of medicines called antihypertensives. Within this group it belongs to a class called beta-blockers.

It works to decrease high blood pressure by reducing the rate and force of the heartbeat and by

widening the arteries and allowing the blood to flow more easily.

Blood pressure is a measurement of the force exerted by the blood circulating in your arteries. It is shown as two values. The first measures blood pressure while the heart muscle is contracting to squeeze out blood (systolic pressure). This is the higher figure. The second measures blood pressure when the heart muscle relaxes between contractions (diastolic pressure). This is the lower figure.

Blood pressure varies from one person to the next, but usually increases as we get older. If you have blood pressure which is higher than normal when measured on three separate occasions, your doctor may diagnose hypertension. High blood pressure does not necessarily cause symptoms. However, if it is severely raised, you may get headaches and a fast or irregular heartbeat (palpitations) and feel quite unwell. It is important to reduce high blood pressure because it can cause stroke, heart attack, heart failure and damage to other body organs, especially the kidneys.

Your doctor may have prescribed this medicine for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

This medicine is available only with a doctor's prescription and is given intravenously by a doctor or nurse in a hospital.

Before you are given TRANDATE

When you must not be given it

You must not be given TRANDATE if you have an allergy to:

- any medicine containing labetalol
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

You must not be given TRANDATE if you have

- a slow or irregular heartbeat
- cardiogenic shock (a serious heart condition caused by very low blood pressure)
- asthma or on-going lung problems which cause breathing difficulties.

Do not breast-feed if you are given this medicine.

The active ingredient in TRANDATE passes into breast milk and there is a possibility that your baby may be affected.

Do not give this medicine to a child under the age of 18 years.

Safety and effectiveness in children younger than 18 years have not been established.

If you are not sure whether you should be given this medicine, talk to your doctor.

Before you are given it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

This is particularly important if you have had a sudden severe (anaphylactic) reaction to anything in the past.

Tell your doctor if you have or have had any of the following medical conditions:

- liver damage or liver disease
- heart disease, poor circulation or a blood disorder
- thyroid problems
- diabetes
- cataracts, and are due to have them operated on soon
- if you are about to have an operation which will require anaesthesia (a medicine that will put you to sleep during the operation).

Tell your doctor if you are pregnant or plan to become pregnant.

TRANDATE is sometimes used to control pre-eclampsia (high blood pressure brought on by pregnancy). TRANDATE may have unwanted effects in an unborn or new-born baby.

Your doctor can discuss with you the risks and benefits involved for you and your baby if you are treated with TRANDATE.

If you have not told your doctor about any of the above, tell them before you start treatment with TRANDATE.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

You should also tell any health professional who is prescribing a new medication for you that you have been given TRANDATE

Some medicines may interfere with TRANDATE. These include:

- halothane (a medicine used to put you to sleep while undergoing surgery)
- class 1 anti-arrhythmic agents known as calcium channel blockers (e.g. amlodipine, verapamil) which are medicines used to treat high blood pressure,

coronary artery disease (disease affecting the blood vessels of the heart) and irregular heartbeat.

- Non-steroidal anti-inflammatory medicines for relieving pain, stiffness and inflammation (e.g. aspirin, ibuprofen, diclofenac, naproxen, celecoxib)
- Digoxin (a medicine used to treat heart failure)
- radioisotopes (medicines used in special diagnostic procedures)
- adrenaline (a medicine used in serious allergic reactions)

These medicines may be affected by TRANDATE or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while being given this medicine.

How TRANDATE is given

TRANDATE must only be given by a doctor or nurse. The doctor or nurse will prepare your injection

How much is given

Your doctor will decide what dose of TRANDATE you will receive, how often it will be given and how much will be given. The doctor works this out based on the reason your blood pressure needs to be lowered and how quickly this needs to happen.

If your blood pressure needs to be lowered urgently, you may be given a bolus (concentrated dose) injection over one minute, and then repeated, if necessary, at 5-minute intervals until your blood pressure comes down.

If you have pre-eclampsia (high blood pressure caused by pregnancy), very high blood pressure after a heart attack or from some other cause, or if there is a need to lower your blood pressure when you are put to sleep for an

operation, you may be given a much slower continuous diluted infusion (by a drip in a vein) for up to several hours.

You should avoid sitting upright within three hours of being given a TRANDATE infusion, otherwise your blood pressure could drop too low, making you feel very dizzy and faint.

Your doctor will do regular blood tests to make sure TRANDATE is working for you.

How TRANDATE is given

TRANDATE is given as an injection into a vein by a nurse or a doctor, while you are lying down in a hospital.

In case of overdose

If you have been given too much (overdose)

Immediately tell your doctor or nurse or telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), for advice if you think that you or anyone else may have been given too much TRANDATE. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose may include extreme dizziness on sitting up or standing, extremely low blood pressure, a slow heartbeat and difficulty breathing.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given TRANDATE.

This medicine helps most people with high blood pressure, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask the doctor or nurse to answer any questions you may have.

Be sure to tell your doctor or nurse as soon as possible if you do not feel well while you are being given this medicine.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- stuffiness in your nose
- rash, itching
- difficulty breathing
- dry eyes
- in men, problems maintaining an erection

The above list includes the more common side effects of your medicine.

Tell your doctor or nurse immediately if you notice any of the following:

- jaundice (yellowing of your skin and/or eyes), liver problems (hepatitis)
- shortness of breath, swelling of the feet of legs due to fluid build-up (congestive heart failure)
- slow heart rate (bradycardia) and slow irregular heartbeats (heart block)
- sudden rash, itchy skin, swelling of face, lips, tongue and other parts of the body, difficulty breathing or shortness of breath
- faintness or dizziness in the first few hours after being given a bolus injection, or after starting a slow infusion, especially when getting up from a lying or sitting position

The above list includes very serious side effects that may require medical attention. Your doctor or nurse will be watching you carefully for signs of these.

Tell your doctor, nurse or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people. Tell

your doctor if you notice any other effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After being given TRANDATE

Storage

TRANDATE will be stored at the hospital pharmacy or the ward. The injection is kept in a cool dry place where the temperature stays below 30°C and it is protected from light.

Disposal

Hospital staff will dispose of any TRANDATE solution left over after your injection or infusion.

Product description

What it looks like

TRANDATE is a clear colourless liquid supplied in a glass ampoule which contains 20 mL of solution.

Ingredients

Active ingredient(s)

Each TRANDATE ampoule contains 100 mg labetalol as the active ingredient.

Inactive ingredient(s):

TRANDATE also contains:

- Dilute hydrochloric acid or sodium hydroxide
- Water for injections

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

TRANDATE is supplied in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,

Ellerslie,
Auckland
NEW ZEALAND

Telephone: 0800 579 811

Date of Preparation

06 January 2021.
(Based on datasheet dated 06 January 2021)