

TRANDATE™

labetalol hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about TRANDATE tablets. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking TRANDATE against the benefits he or she expects it will have.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

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

What TRANDATE is used for

The name of your medicine is TRANDATE. The active ingredient is called labetalol hydrochloride.

Labetalol hydrochloride belongs to a group of medicines called the beta-blockers. The beta-blockers are used for the treatment of high blood pressure (hypertension).

TRANDATE is used for the treatment of all degrees of hypertension. Hypertension is a condition marked by high blood pressure.

TRANDATE is used to lower high blood pressure. It works by changing the body's response to some nerve impulses. Therefore, it widens the blood vessels in the body, causing the blood pressure to fall.

Your doctor may have prescribed this medicine for another condition.

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

TRANDATE tablets are only available with a doctor's prescription.

Before you take it

When you must not take it

Do not take TRANDATE if you are allergic to:

- labetalol hydrochloride or any other agents used to treat hypertension
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction to TRANDATE may include red, itchy skin rashes, difficulty in breathing, swelling of the face, lips, mouth or throat, faintness or shortness of breath.

Do not use TRANDATE after the expiry date (EXP.) printed on the pack.

Do not take it if the packaging is torn or shows signs of tampering.

Before you start to take it

You must tell your doctor if:

- **you are allergic to any other medicines or any foods, dyes or preservatives**

- **you are pregnant or intend to become pregnant.**

TRANDATE is rated in Australia as a Category C drug for the use in pregnancy. TRANDATE should **not** be taken early in pregnancy.

If it is necessary for you to take TRANDATE later in your pregnancy, your doctor will discuss the risks and benefits of taking it.

- **you are breast-feeding or intend to breast-feed.**

TRANDATE is able to pass into breast milk. There is a possibility that the breast-fed baby may be affected. Therefore, do **not** take it if you are breast-feeding or plan to breast-feed.

Tell your doctor if you have or have had any other medical conditions/ health problems, especially the following:

- breathing problems such as asthma
- any other heart problems
- allergic disorders including hay fever
- diabetes
- kidney problems
- liver problems such as jaundice
- an overactive thyroid gland
- any blood vessel disorders causing poor circulation in the arms and legs
- phaeochromocytoma, which is a rare tumour of the adrenal gland
- certain types of angina such as Prinzmetal angina or variant angina
- shock or severe low blood pressure

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

Taking other medicines

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

SOME of these medicines may interfere with TRANDATE. These include:

- medicines used to treat angina or an irregular heart beat
- other medicines used to treat high blood pressure such as verapamil, clonidine and methyldopa
- fluid tablets, also called diuretics
- some medicines used during surgery and emergency situations such as anaesthetics
- cimetidine, a medicine commonly used to treat stomach ulcers
- some medicines used to treat depression
- guanethidine, a medicine used to treat certain heart conditions
- insulin or other medicines used to treat diabetes
- some medicines used to treat fever, pain and inflammation such as paracetamol and aspirin (NSAIDs)

The above medicines either reduce the effectiveness of TRANDATE, reduce its own effectiveness and/or react with TRANDATE resulting in untoward or sometimes dangerous side effects.

This list is not exhaustive. Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking TRANDATE.

Tell your doctor or pharmacist that you are taking TRANDATE before you start to take any other medicine.

How to take it

Your doctor will tell you how much TRANDATE to take and when to take it.

Take it exactly as directed by your doctor.

How much to take

The dose of TRANDATE may vary from patient to patient. Your doctor will decide on the right dose for you.

Adults:

The usual starting dose is 100 to 200 mg twice daily. Your doctor may change this dose depending on how you respond to TRANDATE.

Elderly patients may need smaller doses.

Do not change your dose of TRANDATE unless your doctor tells you to do so.

This medicine is not recommended for use in children.

How to take it

Swallow TRANDATE tablets with a glass of water.

When to take it

It is best to take your TRANDATE tablets immediately after meals.

How long to take it

To properly control your blood pressure, TRANDATE must be taken every day.

Continue taking TRANDATE as long as your doctor recommends it.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take your dose as soon as you remember, and then go back to taking it as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect. If you are unsure about whether to take your next dose, speak to your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (Overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to casualty at your nearest hospital, if you think that you or anyone else may have taken too much TRANDATE. Do this even if there are no signs of discomfort or poisoning. Also, report any other medicine or alcohol which has been taken. You may need urgent medical attention.

Keep telephone numbers for these places handy.

If you take too much TRANDATE you may have the following symptoms: nausea, vomiting, dizziness, light-headedness, faintness, and a very slow heart beat.

While you are using it

Things you must do

Immediately stop taking TRANDATE if a skin rash or any other allergic reaction occurs.

If you become pregnant while taking TRANDATE, tell your doctor immediately.

If you are being treated for diabetes, make sure you check your blood sugar level regularly. TRANDATE may affect how well your diabetes is being controlled. It may also cover up some of the symptoms of low blood sugar such as fast heart beat.

This medicine may also make low blood sugar last longer. Your doctor may need to change your dose of diabetic medicines, including insulin.

If you have to have any medical tests, tell your doctor you are taking TRANDATE.

It may affect the results of some tests.

Tell your doctor if you do not feel TRANDATE is helping your condition.

Visit your doctor regularly.

Your doctor needs to check your progress and see whether you need to stop taking TRANDATE.

Always discuss with your doctor any problems or difficulties during or after taking TRANDATE.

Things you must not do

Do not take any other medicines while you are taking TRANDATE, without first talking to your doctor.

Do not stop taking TRANDATE without first checking with your doctor.

Your doctor may want you to gradually reduce the amount of TRANDATE you are taking before stopping completely. This may help reduce the possibility of heart complications occurring.

Do not give this medicine to anyone else, even if his or her symptoms seem similar to yours.

Things to be careful of

Do not drive or operate machinery until you know how TRANDATE affects you.

TRANDATE may cause dizziness, light-headedness or drowsiness in some people.

Try to get up slowly when you are getting up from a sitting or lying position, as you may feel dizzy, light-headed, or faint.

If you continue to feel unwell, please contact your doctor.

Make sure you drink a lot of water while you are taking TRANDATE.

If you do not drink enough water, you may begin to feel faint, light-headed, or sick. This is because your blood pressure is dropping suddenly. If you continue to feel unwell, please contact your doctor.

Side effects

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

This medicine helps most people with the medical condition listed in the beginning of this leaflet, but it may have unwanted side effects in some people.

All medicines 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 your doctor or pharmacist any questions you may have.

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

- Dizziness
- Light-headedness
- Headache
- Tiredness
- Lack of energy
- Depressed mood
- Blurred vision
- Dry, red or sore eyes
- Muscle cramps
- Unusual movements including tremor
- Tingling of the skin, especially the scalp
- Fever or chills
- Nausea (feeling sick)
- Upset stomach
- Vomiting
- Swelling of the ankles
- Problems with sexual function
- Blocked nose
- Increased sweating

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

- Feeling generally unwell, sometimes yellowing of the skin and/or eyes (jaundice)
- Slow or irregular heart beat
- Skin rashes which include redness, itching or hives
- Difficulty passing urine or unable to pass urine

If any of the following occur, tell your doctor immediately or go to casualty at your nearest hospital:

- Chest tightness, wheezing or shortness of breath
- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing

Some people may get other side effects while taking TRANDATE.

Check with your doctor as soon as possible if you have any problems while taking TRANDATE, even if you do not think the problems are connected with this medicine or are not listed in this leaflet.

After using it

Storage

Keep your tablets in the bottle they were provided in until it is time to take them.

Keep it where children cannot reach it.

A locked cupboard at least one and a half metres above the floor is a good place to store medicines.

Keep your medicine in a cool dry place where the temperature stays below 25°C and protect from light.

Do not store it, or any other medicines in a bathroom or near a sink.

Do not leave it in the car or on windowsills.

Heat and dampness can destroy some medicines.

Do not take TRANDATE if the tablets do not look quite right.

Disposal

If your doctor tells you to stop taking this medicine OR it has passed its expiry date, ask your pharmacist what to do with any left over.

- TRANDATE 100 mg tablets:
AUST R 12521
- TRANDATE 200 mg tablets:
AUST R 12522

This leaflet was updated in June 2012.

Product description

What it looks like

TRANDATE tablets (oral) come in 2 strengths:

- 100 mg, orange, film-coated, biconvex tablets embossed "TRANDATE 100" on one face, in bottles of 100.
- 200 mg, orange, film-coated, biconvex tablets embossed "TRANDATE 200" on one face, in bottles of 100.

Ingredients

Active ingredient:

- Labetalol hydrochloride

Other ingredients:

- Lactose
- Starch - maize
- Starch - pregelatinised maize
- Magnesium stearate
- Methyl hydroxybenzoate
- Propyl hydroxybenzoate
- Pharmacoat 606
- Opaspray M-1-3499D

TRANDATE is gluten and sucrose free, however contains lactose.

Sponsor

Aspen Pharma Pty Ltd
34-36 Chandos Street
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Australia

Australian Registration Numbers: