

# TRANTALOL TABLET

Labetalol hydrochloride (100mg, 200mg)

## What is in the leaflet?

1. What TRANTALOL is used for
2. How TRANTALOL works
3. Before you use TRANTALOL
4. How to use TRANTALOL
5. While you are using it
6. Side effects
7. Storage and Disposal of TRANTALOL
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

## What TRANTALOL is used for

TRANTALOL is used to lower high blood pressure, also called hypertension

## How TRANTALOL works

TRANTALOL contains the active ingredient Labetalol hydrochloride. It belongs to a group of medicine called beta blocker.

It works by changing the body's response to some nerve impulses. As a result, it widens blood vessels in the body causing blood pressure to fall.

## Before you use TRANTALOL

### - When you must not use it

Do not take this medicine if you have an allergy to:

- Labetalol hydrochloride, the active ingredient
- any of the other ingredients listed at the end of this leaflet

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

### - Before you start to use it

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

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

- certain other heart problems, including uncontrolled heart failure
- very slow heart beat, less than 45-50 beats per minute
- asthma, wheezing, difficulty breathing or other lung problems
- low blood pressure
- untreated tumour of the adrenal gland (phaeochromocytoma)
- a disturbance of the body's acid-base balance
- blood circulatory problems

If you have not told your doctor about any of the above, tell him/her before you start taking TRANTALOL.

### - Taking other medicines

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

Some medicines and TRANTALOL may interfere with each other.

These include:

- Tricyclic antidepressants, a group of medicines used to treat depression
- Cimetidine, a medicine commonly used to treat stomach ulcers
- Certain medicines used to treat an irregular heartbeat (e.g. disopyramide, quinidine, amiodarone).
- Calcium channel blockers, medicines used to treat high blood pressure and angina (e.g. verapamil, diltiazem, bepridil, nifedipine)
- Some medicines used during surgery and emergency situations such as anaesthetics

- Other blood pressure medication (e.g. clonidine, methyldopa).
- Fluid tablets, also called diuretics
- Insulin and other antidiabetic medicines

These medicines may be affected by TRANTALOL 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 taking this medicine.

## How to use TRANTALOL

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

### - How much to use

Your doctor will tell you how much TRANTALOL you need to take each day. It is important that you take TRANTALOL as directed by your doctor. Do not take more than the recommended dose.

The usual starting dose of TRANTALOL for adults is one 100mg tablet twice daily.

The use of TRANTALOL is not recommended for children.

### - When to use it

Tablets should be taken with food. The first dose is best taken in the evening at bedtime.

### - How long to use it

TRANTALOL helps to control your condition but does not cure it. Therefore TRANTALOL must be taken every day. Continue taking TRANTALOL for as long as your doctor prescribes.

- If you forget to use it

Take your dose as soon as you remember, and continue to take it as you would normally.

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

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 not sure what to do, ask your doctor or pharmacist.

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

- If you use too much (overdose)

Immediately telephone your doctor for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much TRANTALOL.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

**While you are using it**

- Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking TRANTALOL.

Tell any other doctors, dentists or pharmacists who treat you that you are taking TRANTALOL.

Tell your doctor if you develop a skin rash or hives, or you become pregnant while taking TRANTALOL.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking TRANTALOL. It may affect other medicines used during surgery.

If you are going to have any blood tests, tell your doctor that you are taking TRANTALOL. It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

- Things you must not do

Do not take TRANTALOL to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not stop taking TRANTALOL or lower the dosage without checking with your doctor. If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects such as chest pain, irregular heart beat and high blood pressure. If possible your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

- Things to be careful of

Be careful of driving or operating machinery until you know how TRANTALOL affects you.

TRANTALOL may cause dizziness, light-headedness or tiredness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking TRANTALOL. Alcohol can affect the way in which TRANTALOL works.

**Side effects**

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

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

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

- Dizziness or light-headedness, especially when getting up quickly
- Headache
- Tiredness, lack of energy
- Depressed mood
- Tingling of the skin, especially the scalp
- Nausea, vomiting or stomach upset
- Blocked nose, sweating, swollen ankles

The above list includes the more common side effects of TRANTALOL. They are usually mild and short-lived.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers → Reporting).

**Storage and Disposal of TRANTALOL**

- Storage

Keep your medicine in the original container. If you take it out of its original container it may not keep well.

Keep your medicine in a place where the temperature stays below 25°C.

Do not store TRANTALOL or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

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

- Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

**Product Description**

- What it looks like

TRANTALOL TABLET 100MG

A yellow, round, 9mm diameter tablet with marking 'duo' and scored on another side.

Government tender: A yellow, round, 9mm diameter tablet with marking 'duo' and 'KKM' (scored).

TRANTALOL TABLET 200MG

A yellow, round, 9mm diameter tablet with marking 'd' and scored on another side.

- Ingredients

Active ingredient

TRANTALOL TABLET 100MG

- Each tablet contains 100mg labetalol hydrochloride

TRANTALOL TABLET 200MG

- Each tablet contains 200mg labetalol hydrochloride

Inactive ingredients:

TRANTALOL TABLET 100MG

- Aerosil
- Promigel
- Quinoline Yellow
- Corn Starch
- Magnesium stearate
- Lactose
- Colloidal silicon dioxide

TRANTALOL TABLET 200MG

- Aerosil
- Promigel
- Quinoline Yellow
- Corn Starch
- Magnesium stearate
- Lactose
- Colloidal silicon dioxide

- MAL number(s)

TRANTALOL TABLET 100MG  
MAL19890589A

TRANTALOL TABLET 200MG  
MAL19890590A

**Manufacturer**

DUOPHARMA (M) SDN. BHD.  
(42491-M)  
Lot. 2599, Jalan Seruling 59,  
Kawasan 3, Taman Klang Jaya,  
41200 Klang, Selangor Darul Ehsan,  
Malaysia.

**Product Registration Holder**

DUOPHARMA (M) SDN. BHD.  
(42491-M)  
Lot. 2599, Jalan Seruling 59,  
Kawasan 3, Taman Klang Jaya,  
41200 Klang, Selangor Darul Ehsan,  
Malaysia.

**Date of Revision**

02/05/2014