1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

TRANDATE INJECTION 5 mg/ml

Labetalol hydrochloride

Sugar free

Read all of this leaflet carefully before TRANDATE INJECTION is administered

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor pharmacist nurse or other healthcare provider.
- TRANDATE INJECTION has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What TRANDATE INJECTION is and what it is used for
2. What you need to know before you receive TRANDATE INJECTION
3. How to receive TRANDATE INJECTION
4. Possible side effects
5. How to store TRANDATE INJECTION
6. Contents of the pack and other information

1. What TRANDATE INJECTION is and what it is used for

TRANDATE INJECTION belongs to a group of medicines called beta blockers.

TRANDATE INJECTION decreases high blood pressure by reducing the rate and force of the heartbeat and by widening arteries and helping blood flow.

TRANDATE INJECTION is given in hospital.

TRANDATE INJECTION is used when a person's blood pressure needs to be reduced very quickly. It can be used to lower very high blood pressure in pregnant women.

TRANDATE INJECTION is sometimes used by anaesthetists to keep your blood pressure down during operations.

If you are not sure why you have been given this injection, ask your doctor.

2. What you need to know before you receive TRANDATE INJECTION

TRANDATE INJECTION should not be administered to you if:

- you are hypersensitive (allergic) to labetalol or any of the other ingredients of TRANDATE INJECTION (listed in section 6).
- you have second or third degree heart block, or a condition where your heart suddenly can't pump enough blood (cardiogenic shock), chest pain caused by reduced blood flow to the heart (angina) or any other heart problem causing very low blood pressure or a slow heartbeat.
- you have low cardiac output (where not enough blood is being squeezed out of the heart with each beat) after a heart attack.
- your heart cannot maintain adequate circulation of blood (cardiogenic shock).
- you have heart failure that is out of control or not responding to treatment with digitalis.
- you have a heart defect that leads to a decreased function of the heart (heart block).
- your heart has difficulty pumping the proper amount of blood to the

body's tissues.

- you have a problem that is common in the elderly, related to poor control of the working of your heart (sick sinus syndrome).
- you suffer from angina (chest pains) when at rest.
- you suffer from wheezing, obstructive airways disease or asthma – taking TRANDATE INJECTION can make your breathing worse.
- you have a weak heart or a very slow heartbeat (less than 45 or 50 beats per minute).
- you are breastfeeding.

TRANDATE INJECTION is not suitable for children.

Warnings and precautions

Tell your doctor or healthcare provider before being given the injection:

Take special care with TRANDATE INJECTION if:

- you are allergic to any other medicines, insect stings, foods, dyes or preservatives. This is particularly important if you have had a sudden severe (anaphylactic) reaction to anything in the past.
- you are pregnant or plan to become pregnant. If you are trying to get pregnant and need a TRANDATE INJECTION for another condition, please tell your doctor.
- you are breastfeeding or plan to breastfeed.
- you have kidney problems.
- you have liver damage or liver disease, or if you have had TRANDATE INJECTION before and experienced any liver problems.
- you are about to have an operation which will require anaesthesia (a medicine that will put you to sleep during the operation): as TRANDATE

INJECTION may mask the effects of a sudden loss of blood.

- you are scheduled for cataract surgery as TRANDATE INJECTION 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.
- you have bad circulation in your hands or feet.
- you have a tumour which increases your blood pressure (phaeochromocytoma).
- you have increased acid levels in the blood (metabolic acidosis).
- you are having a medical procedure called MIBG scintigraphy.
- you have hypovolaemia (a state of decreased blood volume).
- you have asthma.
- you have diabetes (increased blood sugar).
- you have thyrotoxicosis (excess of thyroid hormone in the body).
- you have a weak heart or a very slow heartbeat.
- you experience skin rashes and/or dry eyes**.**

Children and adolescents

Safety and efficacy have not been established in children.

Other medicines and TRANDATE INJECTION

Always tell your healthcare provider if you are taking any other medicines. (This includes complementary or traditional medicines).

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

- Medicines used to treat your heart or blood pressure (such as digitalis,

clonidine, hydralazine, disopyramide, quinidine, amiodarone, calcium antagonists such as verapamil, alpha blockers such as doxazosin, diltiazem, nifedipine, ACE inhibitors, angiotensin-II antagonists, and diuretics (water tablets)).

- Class I antidysrhythmic medicines for irregular heart rhythms or medicines known as calcium channel blockers, which are used for high blood pressure, coronary artery disease (affecting blood vessels in the heart), and irregular heart rhythms.
- Non-steroidal anti-inflammatory, corticosteroids or other medicines for relieving pain, stiffness and inflammatory conditions.
- Insulin or oral antidiabetic medicines.
- Medication to treat mental disorders i.e. phenothiazines such as chlorpromazine.
- Medicines to treat depression (such as monoamine oxidase inhibitors or tricyclic antidepressants).
- Digoxin (Digitalis), which is used to treat irregular heart rhythm.
- Certain medicines given in hospital such as epinephrine (adrenaline), which stimulates the heart.
- Ergot derivatives and cholinesterase inhibitors used to treat Parkinson's disease.
- Anaesthetic medicines (such as cyclopropane, trichloroethylene, alcohol, barbiturates).
- Anxiolytic and hypnotic medicines (clonidine) for anxiety and sedation.
- Any other medicine, including medicines obtained without a prescription.

Taking TRANDATE INJECTION, at the same time as the medicines 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 medicines listed above.
The results of blood or urine tests may be affected by taking TRANDATE INJECTION. If you need to have a blood or urine test, tell your doctor that you have been given TRANDATE INJECTION.

Pregnancy, breastfeeding and fertility

The safety of TRANDATE INJECTION during pregnancy and whilst breastfeeding has not been established. Nipple pain and Raynaud's phenomenon of the nipple have been reported (see section 4).
TRANDATE INJECTION is sometimes used to control pre-eclampsia (high blood pressure brought on by pregnancy). TRANDATE INJECTION may have unwanted effects in an unborn or new-born baby. If you are trying to get pregnant and need a TRANDATE INJECTION for another condition, please tell your doctor.
The active ingredient in TRANDATE INJECTION, labetalol, passes into breast milk. Do not breastfeed after receiving a TRANDATE INJECTION until you doctor says it is alright to do so.

If you are pregnant or breastfeeding think you may be pregnant or are planning to have a baby please consult your doctor, pharmacist or other healthcare provider before receiving TRANDATE INJECTION.

Driving and using machines

It is not always possible to predict to what extent TRANDATE INJECTION may interfere with your daily activities. You should ensure that you do not engage in

the above activities until you are aware of the measure to which TRANDATE INJECTION affects you (see section 4).

3. How to receive TRANDATE INJECTION

TRANDATE INJECTION is given in hospital as an injection into a vein by a person who is qualified to do so.
You will never be expected to give yourself TRANDATE INJECTION.

You should only be given this medicine if you are lying down. You should not start to sit upright within three hours of starting a TRANDATE INJECTION infusion; otherwise your blood pressure could drop down too far, making you feel very dizzy and faint.
Your doctor will calculate your dose, depending on the reason why your blood pressure needs to be lowered and how quickly this needs to happen. If you have the impression that the effect of TRANDATE INJECTION is too strong or too weak, tell your doctor or pharmacist.
Your doctor will do regular blood tests to make sure TRANDATE INJECTION is working for you.

If you receive more TRANDATE INJECTION than you should

Since a healthcare provider will administer this medicine, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to receive TRANDATE INJECTION

Since a healthcare provider will administer TRANDATE INJECTION, it is unlikely that the dose will be missed.

4. Possible side effects

TRANDATE INJECTION can have side effects.

Not all side effects reported for TRANDATE INJECTION are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TRANDATE INJECTION, please consult your healthcare provider for advice.

If any of the following happens, stop receiving TRANDATE INJECTION and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to TRANDATE INJECTION. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Jaundice (yellowing of your skin), liver problems (hepatitis), hepatic necrosis that is characterised by easy bleeding, swollen stomach, disorientation and/or sleepiness,
- TRANDATE INJECTION can cause bradycardia (slow heart rate) and heart block (slow irregular heartbeats). Your doctor or nurse will monitor you carefully for signs of these side effects,
- heart failure causing shortness of breath with swelling of the feet and

ankles.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Faintness or dizziness in the first few hours after being given TRANDATE INJECTION,
- mental disturbances such as confusion or disorientation,
- stuffiness in your nose,
- evidence of liver or kidney damage,
- not being able to ejaculate.

Less frequent side effects:

- Drug fever where you develop a fever with possible chills, headache, extreme tiredness, fast heart rate and a general feeling of unwellness,
- worsening of Raynaud's syndrome which makes the toes and fingers go numb and pale due to poor blood circulation,
- difficulty breathing because the airways have narrowed.

Side effects with unknown frequency:

- 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 you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to **SAHPRA:** via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8:

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088/ +27 (0)11 239-6200

By reporting side effects, you can help provide more information on the safety of TRANDATE INJECTION.

5. How to store TRANDATE INJECTION

Store all medicines out of reach of children.

Store at or below 30 °C and protect from light.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What TRANDATE INJECTION contains

The active substance is 5 mg of labetalol hydrochloride in each 1 ml.

The other ingredients are dilute hydrochloric acid (for pH adjustment), sodium hydroxide (for pH adjustment), water for injection.

Sugar free.

What TRANDATE INJECTION looks like and contents of the pack

TRANDATE INJECTION is a clear, colourless solution.

1 x 20 ml clear Type 1 glass ampoule. 5 ampoules are packed in an outer cardboard carton together with a leaflet.

Not all packs or pack sizes may be marketed.

Holder of the certificate of registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 118 088/ +27 (0)11 239-6200

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Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information

Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

Botswana: B9303870 S2
Namibia: NS2 90/7.13/00587

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