

Applicant/PHRC: **RBC PHARMACEUTICALS (PTY) LTD.**

Product proprietary name: **Labetalol 5 mg/ mL RBC**

Dosage form and strength: **Labetalol Hydrochloride, Injection, 5 mg/mL**

APPROVED PATIENT INFORMATION LEAFLET Labetalol 5 mg/ mL RBC

SCHEDULING STATUS:

S3

Labetalol 5 mg/mL RBC

Labetalol hydrochloride

Sugar free

Read this full leaflet carefully before your medical practitioner administers Labetalol 5 mg/mL RBC

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other health care provider.
- Labetalol 5 mg/mL RBC 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 Labetalol 5 mg/mL RBC is and what it is used for.
2. What you need to know before your doctor administers Labetalol 5 mg/mL RBC.
3. How Labetalol 5 mg/mL RBC will be given to you.
4. Possible side effects that you may experience.
5. How to store Labetalol 5 mg/mL RBC.
6. Contents of the pack and other information.

1. What Labetalol 5 mg/mL RBC is and what it is used for.

Labetalol 5 mg/mL RBC belongs to a group of medicines called beta blockers. Labetalol 5 mg/mL RBC decreases high blood pressure by reducing the rate and force of the heartbeat and by

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widening arteries and helping blood flow. Labetalol 5 mg/mL RBC is given in the hospital.

Labetalol 5 mg/mL RBC 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.

Labetalol 5 mg/mL RBC 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 are given Labetalol 5 mg/mL RBC.

Labetalol 5 mg/mL RBC should not be given to you if:

- you are hypersensitive (allergic) to labetalol or any of the other ingredients of Labetalol 5 mg/mL RBC (listed in section 6).
- you have a 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 (heart block) that leads to a decreased function of the heart.
- 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 Labetalol 5 mg/mL RBC 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.
- you have a tumour near your kidneys (phaeochromocytoma)
- you have increased acid levels in the blood (metabolic acidosis)

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- you have low blood pressure (hypotension)
- you have very bad circulation, especially in your hands and feet.

Labetalol 5 mg/mL RBC is not suitable for children.

Warnings and precautions

Tell your doctor or health care provider before being given the Labetalol 5 mg/mL RBC:

Special care should be taken with Labetalol 5 mg/mL RBC if:

- you are allergic to labetalol hydrochloride.
- you are allergic to any of the other ingredients of Labetalol Injection (see section 6).
- you are pregnant or plan to become pregnant. If you are trying to get pregnant and need a Labetalol 5 mg/mL RBC for another condition, please tell your doctor.
- you are breastfeeding or plan to breastfeed.
- 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 labetalol can make your breathing worse.
- you have a tumour near your kidneys (phaeochromocytoma).
- you have increased acid levels in the blood (metabolic acidosis).
- you have a weak heart or a very slow heartbeat (less than 45 or 50 beats per minute).
- you have low blood pressure (hypotension).
- you have liver disease or your liver was affected when taking labetalol in the past.
- you have very bad circulation, especially in your hands and feet.

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

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Check with your doctor before you are given Labetalol Injection if:

- you are about to receive an anaesthetic: as labetalol may mask the effects of a sudden loss of blood.
- you suffer or have suffered from any serious allergic reactions in the past.
- you have ever suffered from a skin condition called psoriasis.
- you have kidney or liver problems.
- you are receiving a procedure called MIBG scintigraphy (often used to detect certain tumours).
- 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.

Sodium contents

This medicinal product contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium- free'

Children and adolescents

Safety and efficacy have not been established in children.

Other medicines and Labetalol 5 mg/mL RBC

Always tell your healthcare professional if you are taking any other medicine.

(This includes complimentary, over-the-counter traditional medicines).

The effect of Labetalol 5 mg/mL RBC may be altered when it is received together with

- 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, xamoterol and diuretics (water tablets).

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- Medicines to treat depression (such as monoamine oxidase inhibitors or tricyclic antidepressants).
- Anxiolytic and hypnotic medicines for anxiety and sedation.
- NSAIDs, corticosteroids or other medicines to treat pain or inflammatory conditions.
- Cimetidine used to treat stomach ulcers
- Insulin or oral anti-diabetic medicines.
- Anaesthetic medicines (such as cyclopropane, trichloroethylene, alcohol, barbiturates).
- Phenothiazines such as chlorpromazine.
- Antimalarial medicines such as halofantrine, mefloquine or quinine.
- Medicines for stimulating the heart e.g., adrenaline.
- Ergot derivatives used to treat Parkinson's disease.
- Tropisetron used to treat nausea.
- Alprostadil and moxislyte to treat impotence.
- Aldesleukin for the treatment of secondary cancer of the kidney.
- Hormones such as oestrogen and progesterone used as contraceptives or for hormone replacement therapy.
- Any other medicine, including medicines obtained without a prescription.

Taking Labetalol 5 mg/mL RBC 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 labetalol. If you need to have a blood or urine test, tell your doctor that you have been given Labetalol 5 mg/mL RBC Injection.

Pregnancy, breast-feeding and fertility

The safety of Labetalol 5 mg/mL RBC during pregnancy and whilst breastfeeding has not been established. Labetalol 5 mg/mL RBC is sometimes used to control pre-eclampsia (high blood pressure brought on by pregnancy).

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Labetalol 5 mg/mL RBC may have unwanted effects in an unborn or new-born baby. If you are trying to get pregnant and need a Labetalol 5 mg/mL RBC for another condition, please tell your doctor.

Breastfeeding

The active ingredient in Labetalol 5 mg/mL RBC, labetalol, passes into breast milk. Do not breastfeed after receiving a Labetalol 5 mg/mL RBC until your doctor says it is all right 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 Labetalol 5 mg/mL RBC.

Driving and using machines

It is not always possible to predict to what extent Labetalol 5 mg/mL RBC 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 Labetalol 5 mg/mL RBC affects you (see section 4).

3. How to receive Labetalol 5 mg/mL RBC

Labetalol 5 mg/mL RBC 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 Labetalol 5 mg/mL RBC.

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 Labetalol 5 mg/mL RBC 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 Labetalol 5 mg/mL RBC is too strong or too weak, tell your doctor or pharmacist. Your doctor will do regular blood tests to make sure Labetalol 5 mg/mL RBC is working for you.

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If you are given more Labetalol 5 mg/mL RBC than you should receive

It is unlikely that you will be given too much Labetalol 5 mg/mL RBC. This will be monitored during your operation.

If you forget to receive Labetalol 5 mg/mL RBC:

Since the health care provider will administer Labetalol 5 mg/mL RBC, it is unlikely that the dose will be missed.

4. Possible side effects:

Like all medicines, Labetalol 5 mg/mL RBC can cause side effects, although not everybody gets them. If side effects occur, they usually do so while you are asleep. Your doctor will monitor these effects during your operation.

Not all side effects reported for Labetalol 5 mg/mL RBC are included in this leaflet. Should your general health worsen while receiving Labetalol 5 mg/mL RBC, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happens, stop receiving Labetalol 5 mg/mL RBC and tell your doctor immediately or go to the casualty department at your nearest hospital:

- severe skin rash, itching or hives
- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing. These are all very serious side effects. If you have them, you may have had a serious allergic reaction to Labetalol 5 mg/mL RBC. 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)

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- Labetalol 5 mg/mL RBC 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 Labetalol 5 mg/mL RBC
- rashes
- mental disturbances such as confusion or disorientation,
- heart pain or heart attack
- decreased blood pressure
- stuffiness in your nose
- evidence of liver or kidney damage
- raised liver functional tests
- muscle spasm
- not being able to ejaculate

Less frequent side effects:

- high body temperature
- high potassium levels in the body
- sleep disturbances
- nightmares
- mood depression
- imaginings
- headache,
- tiredness,

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- dizziness,
- tremor
- impaired vision
- eyes are feeling dry
- decreased heart rate
- heart block
- abnormal liver functions
- sweating
- worsening of Raynaud's syndrome
- difficulty breathing because the airways have narrowed
- swelling (fluid accumulation)
- decreased sugar levels

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or health care professional. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website. By reporting side effects, you can help provide more information on the safety of Labetalol 5 mg/ mL RBC.

5. How to store Labetalol 5 mg/mL RBC

Storage will be handled by healthcare professionals.

Store at or below 25 °C.

Keep the vials in the carton until required for use.

Do not use it after the expiry date on the label and carton.

Do not throw medicines in drains or sewerage systems (e.g., toilets).

Keep all medicines out of reach and sight of children.

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6. Contents of the pack and other information

What Labetalol 5 mg/mL RBC contains:

The active substance is Labetalol hydrochloride.

Each mL contains Labetalol Hydrochloride 5 mg.

The other ingredients:

Citric acid Monohydrate

Dextrose anhydrous

Edetate Disodium Dihydrate

Methylparaben

Nitrogen

Propylparaben

Sodium Hydroxide

Water for Injection

What Labetalol 5 mg/mL RBC looks like and contents of the pack:

Clear colourless solution filled in a vial.

Labetalol 5 mg/mL is packed in a 1 X 20 mL vial pack.

REGISTRATION NUMBER

57/7.1.3/0906

Holder of Certificate of Registration

RBC PHARMACEUTICALS (PTY) LTD.

23 Kiaat Street, ERF 926, Extension 7,

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This leaflet was last revised on:

TBA

For any information about this medicine, please contact the local representative of the Holder of

Certificate of Registration: RBC PHARMACEUTICALS (PTY) LTD. Tel: +27 10 224 0999

Other sources of information

Detailed information on this medicine is available on the RBC PHARMACEUTICALS (PTY) LTD

web site: <http://www.rbcpharma.com>