1.3.2 PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

IMMAROC solution for infusion

Rocuronium bromide

Each ml IMMAROC contains 3.30 mg of sodium

Read all of this leaflet carefully before you start taking IMMAROC

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- IMMAROC 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 IMMAROC IS AND WHAT IT IS USED FOR

IMMAROC is one of a group of medicines called muscle relaxants.

Muscle relaxants are used during an operation as part of a general anaesthetic. When you have an operation your muscles must be completely relaxed. This makes it easier for the surgeon to perform the operation.

IMMAROC can also be used in Intensive Care Units to keep your muscles relaxed.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE IMMAROC

You should not receive IMMAROC

If you are hypersensitive (allergic) to rocuronium, the bromide ion or any of the other ingredients of IMMAROC.

There is insufficient data to support the use of IMMAROC in babies (0 to 1 month).

IMMAROC is not recommended for the facilitation of mechanical ventilation in the intensive care in children and elderly patients in the Intensive Care Unit (ICU).

The safety in pregnancy and lactation has not been demonstrated.

Warnings and precautions

Talk to your anaesthetist before you receive this medicine:

• if you are allergic to muscle relaxants

• if you have had kidney, heart, liver or gall bladder disease

• if you have had diseases affecting nerves and muscles

• if you have fluid retention (oedema).

Tell your anaesthetist if any of these applies to you.

Some conditions may influence the effects of IMMAROC — for example:

- low calcium levels in the blood
- low potassium levels in the blood
- high magnesium levels in the blood
- low levels of protein in the blood

- too much carbon dioxide in the blood
- loss of too much water from the body, for example by being sick, diarrhoea or sweating
- over-breathing leading to too little carbon dioxide in the blood (alkalosis)
- general ill-health
- burns
- being very overweight (obesity)
- very low body temperature (hypothermia).

If you have any of these conditions, your anaesthetist will take it into account when deciding the correct dose of IMMAROC for you.

Other medicines and IMMAROC

Tell your anaesthetist if you are taking other medicines or have recently taken them. This includes medicines or herbal products that you have bought without a prescription.

IMMAROC may affect other medicines or be affected by them.

Medicines which increase the effect of IMMAROC:

• certain antibiotics

• certain medicines for heart disease or high blood pressure (water tablets, calcium channel blockers, beta-blockers and quinidine)

• certain anti-inflammatory medicines (corticosteroids)

• medicines for manic depressive illness (bipolar disorder) • magnesium salts

• certain medicines used to treat malaria.

Medicines which decrease the effect of IMMAROC:

• certain medicines for epilepsy

• calcium chloride and potassium chloride

• certain protease inhibitors called gabexate and ulinastatin.

In addition, you may be given other medicines before or during surgery which can alter the effects of IMMAROC. These include certain anaesthetics, other muscle relaxants, medicines such as phenytoin and medicines which reverse the effects of IMMAROC. IMMAROC may make certain anaesthetics work more quickly. Your anaesthetist will take this into account when deciding the correct dose of IMMAROC for you.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, inform your doctor, anaesthetist or other healthcare professional.

Driving and using machines

Your doctor will inform you when it is safe to drive and operate potentially dangerous machinery after you have been administered IMMAROC.

Do not drive or use any tools or machines if you feel tired or sleepy from the treatment with IMMAROC.

3. HOW IMMAROC SOLUTION FOR INFUSION IS GIVEN

Dosage

The doctor will determine the dose. You will be given IMMAROC before and/or during a surgical procedure. During the procedure it will be checked whether IMMAROC is still working. You may be given additional doses if they are needed.

Method and route of administration

IMMAROC will be given to you by your anaesthetist. IMMAROC is given intravenously (into the vein), either as single injections or as a continuous infusion (a drip).

If you are administered more IMMAROC than you should

As your anaesthetist will be monitoring your condition carefully it is unlikely that you will be given too much IMMAROC. However, if this happens, your anaesthetist will keep you breathing artificially (on a ventilator) until you can breathe on your own. You will be kept asleep while this takes place.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. If these side effects occur while you are under anaesthetic, they will be seen and treated by your anaesthetist.

Less Frequent

- The medicine is too effective, or not effective enough.
- The medicine works for longer than expected.
- Lowering of blood pressure.
- Increase in heart rate.
- Pain near the site of injection.
- Allergic (hypersensitivity) reactions (such as difficulty in breathing, collapse of circulation and shock).
- Wheezing of the chest.
- Muscle weakness.
- Swelling, a rash or redness of the skin.
- Sudden fever with rapid heartbeat, rapid breathing and stiffness, pain and/or weakness in your muscles.

Not all side effects reported for IMMAROC are included in this leaflet. Should your general health worsen or if you experience any untoward side effects while using IMMAROC, please consult your doctor, pharmacist or other healthcare professional for advise

If any of the side effects gets serious or if you notice any side effects not listed in this leaflet:

Tell your anaesthetist or other doctor.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of IMMAROC

5. HOW TO STORE IMMAROC

Store all medicines out of reach of children.

Store at 2^0 – 8^0 C

Store in the original package in order to protect from moisture

Protect from light.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What IMMAROC contains

The active substance of IMMAROC is rocuronium bromide 10 mg/ml.

The other ingredients are sodium chloride.

What IMMAROC looks like and contents of the pack

A clear colourless to yellow orange solution in a pack of 5mL clear glass vial with 20 mm plain grey bromobutyl rubber stopper having 20 mm super green colored aluminium flip-off seal in a unit carton

Holder of Certificate of Registration

Ruby Pharmaceuticals (PTY) LTD

Unit 1, 96 Hartley Road

Durban, 4091

This leaflet was last revised in

Registration Number: