

## Package leaflet: Information for the user

### Rocuronium bromide Tamarang 10 mg/mL solution for injection/infusion Rocuronium bromide

**Read all of this leaflet carefully before you are given this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your anaesthetist or other doctor.
- If you get any side effects, talk to your anaesthetist or other doctor. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet:**

1. What Rocuronium bromide Tamarang is and what it is used for
2. What you need to know before Rocuronium bromide Tamarang is given
3. How Rocuronium bromide Tamarang is given
4. Possible side effects
5. How Rocuronium bromide Tamarang is stored
6. Contents of the pack and other information

#### **1. What Rocuronium bromide Tamarang is and what it is used for**

Rocuronium bromide Tamarang is one of a group of drugs called *muscle relaxants*.

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

Normally the nerves send messages called *impulses* to your muscles. Rocuronium bromide Tamarang acts by blocking these impulses so that the muscles relax. Because the breathing muscles also relax, you will need help to breathe (*artificial ventilation*) during and after your operation until you can breathe on your own again.

During the operation your anaesthetist will keep a check on the effect of the muscle relaxant and if necessary will give you some more. At the end of surgery, the effects of the drug are allowed to wear off and you can start breathing on your own. Sometimes the anaesthetist will give you another drug to help speed this up.

Rocuronium bromide Tamarang can also be used in Intensive Care Unit for short term use to keep your muscles relaxed.

#### **2. What you need to know before Rocuronium Tamarang is given**

##### **You should not receive Rocuronium bromide Tamarang**

- **if you are allergic** (hypersensitive) to rocuronium, the bromide ion or any of the other ingredients of this medicine (listed in section 6).

**Tell your anaesthetist if this applies to you.**

##### **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 the **nerves** and **muscles** (e.g. *poliomyelitis, myasthenia gravis*)
- if you have **fluid retention** (*oedema*)

- if you have a history of malignant hyperthermia (sudden fever with rapid heartbeat, rapid breathing and stiffness, pain and/or weakness in your muscles)

**Some conditions may influence the effects of Rocuronium bromide Tamarang — 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 (*acidosis*)
- loss of too much water from the body, for example by being sick, diarrhoea or sweating (*dehydration*)
- over-breathing leading to too little carbon dioxide in the blood (*alkalosis*)
- general ill-health
- being very overweight (*obesity*)
- burns
- 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 Rocuronium bromide Tamarang for you.

**Children and elderly**

Rocuronium bromide Tamarang can be used in children (newborns and adolescence) and elderly but your anaesthetist should first assess your medical history.

**Other medicines and Rocuronium bromide Tamarang**

**Tell your anaesthetist if you are taking** or have recently taken any other medicines. Rocuronium bromide Tamarang may affect other medicines or be affected by them.

**Medicines which increase the effect of Rocuronium bromide Tamarang:**

- certain **antibiotics**
- certain medicines for **heart diseases** or **high blood pressure** (*water tablets, calcium channel blockers, beta-blockers and quinidine*)
- certain **anti-inflammatory** medicines (*corticosteroids*)
- **magnesium salts**
- certain medicines used for **bipolar disorder** (*lithium salts*)
- certain medicines used to treat **malaria** (*quinine*).
- certain medicines **used to make you sleep** during surgery (*anaesthetics*)
- certain medicines which cause **increased volume of urine** (*diuretics*)
- certain **local anaesthetics** (*lidocaine, bupivacaine*)
- certain medicines for **epilepsy** during an operation (*phenytoin*)
- certain medicines used to **induce short-term muscle relaxation** in anaesthesia and intensive care (*suxamethonium*)

**Medicines which decrease the effect of Rocuronium bromide Tamarang:**

- long term use of medicines for **epilepsy** (*phenytoin and carbamazepine*)
- certain **protease inhibitors** called gabexate and ulinastatin
- acetylcholinesterase inhibitors, medicines for the **treatment of myasthenia gravis** (*e.g. neostigmine, edrophonium, pyridostigmine*)
- **calcium chloride** and **potassium chloride**

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

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your anaesthetist for advice before receiving this medicine.

Your anaesthetist may still give you Rocuronium bromide Tamarang, but you need to discuss it first. Rocuronium bromide Tamarang may be given to you if you are having a Caesarean section. Breastfeeding should be suspended 6 hours after use of this medicine.

### **Driving and using machines**

Do not drive or use machines until advised it is safe to do so. Because Rocuronium bromide Tamarang is given as part of a general anaesthetic, you may feel tired, weak or dizzy for some time afterwards. Your anaesthetist will be able to advise you on how long the effects are likely to last.

### **Rocuronium bromide Tamarang contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per vial/ampoule, that is to say essentially “sodium free”.

## **3. How Rocuronium bromide Tamarang is given**

### **Dose**

Your anaesthetist will work out the dose of Rocuronium bromide Tamarang you need based on:

- the type of anaesthetic
- the expected length of the operation
- other drugs you are taking
- your state of health

The normal dose is 0.6 mg per kg body weight and the effect will last 30 - 40 minutes.

### **How Rocuronium bromide Tamarang is given**

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

This medicinal product is for single use only. Any unused solution for injection/infusion should be discarded.

### **If more Rocuronium bromide Tamarang is given to you than recommended**

As your anaesthetist will be monitoring your condition carefully it is unlikely that you will be given too much Rocuronium bromide Tamarang. However, if it happens, your anaesthetist will keep you breathing artificially (on a ventilator) until you 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.

### **Uncommon**

(may affect up to 1 in 100 people)

- Increase in heart rate
- Lowering of blood pressure
- The drug is too effective or not effective enough
- The drug works for longer than expected

- Pain near the site of injection

### **Very rare**

(may affect up to 1 in 10,000 people )

- Allergic (*hypersensitivity*) reactions (such as difficulty in breathing, collapse of the circulation and shock)
- Wheezing of the chest
- Muscle weakness
- Swelling, a rash or wheals or redness of the skin
- Long term muscle dysfunction usually observed when rocuronium bromide and anti-inflammatory medicines (corticosteroids) are used in the Intensive Care Unit at the same time in critically ill patients (steroid myopathy)
- Airway complication of anaesthesia

### **Not known**

(frequency cannot be estimated from the available data)

- Severe allergic coronary blood vessels spasm (Kounis syndrome) resulting in chest pain (angina) or heart attack (myocardial infarction)

**If any of these side effects get 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 anaesthetist or other doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How Rocuronium bromide Tamarang is stored**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the ampoule/vial label and carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C-8°C).

Do not freeze.

Keep the ampoule/vial in the outer carton in order to protect from light.

Rocuronium bromide Tamarang may also be stored outside the refrigerator at a temperature of up to 25°C for a maximum of 12 weeks.

The solution should be used immediately after opening the ampoule/vial.

**In-use shelf life diluted medicinal product:**

After dilution with infusion fluids, chemical and physical in-use stability has been demonstrated for 24 hours at 25°C. From a microbiological point of view, the diluted product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user/administrator and would normally not be longer than 24 hours at 2 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

Do not use this medicine if you notice that the solution is not clear and not free from particles.

## 6. Contents of the pack and other information

### What Rocuronium bromide Tamarang contains

The active substance is: rocuronium bromide.

Each mL of solution for injection/infusion contains 10 mg rocuronium bromide.

Each ampoule/vial with 5 mL contains 50 mg rocuronium bromide.

Each ampoule/vial with 10 mL contains 100 mg rocuronium bromide.

The other ingredients are:

Sodium acetate trihydrate

Sodium chloride

Acetic acid 99% (for pH adjustment)

Acetic acid 30% (for pH adjustment)

Water for injections

Sodium hydroxide (for pH adjustment)

### What Rocuronium bromide Tamarang looks like and contents of the pack

Rocuronium Tamarang 10 mg/mL solution for injection/infusion is a clear, colourless up to pale brown-yellowish solution.

Ampoules/Vials of 5 and 10 mL

#### Pack sizes:

10 x 5 mL

12 x 5 mL

(6 x 10) x 5 mL

10 x 10 mL

(2 x 10) x 10 mL

Not all pack sizes may be marketed.

### Marketing Authorisation Holder and Manufacturer

{Name and address}

<{tle}>

<{fax}>

<{e-mail}>

<[To be completed nationally]>

**This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:**

Country	Invented Name	Marketing authorisation holder (MAH)
1. Germany (RMS)	Rocuroniumbromid Tamarang 10 mg/mL Injektionslösung/infusionslösung	Tamarang, S.A. Balmes 85 P 2 08008 Barcelona; Spain
2. Italy (CMS)	Rocuronio bromuro Salf 10 mg/mL soluzione iniettabile per uso endovenoso	S.A.L.F S.p.A - Laboratorio Farmacologico Via Marconi, 2 24069 Cenate Sotto (BG), Italy
3. Ireland (CMS)	Rocuronium bromide 10 mg/mL solution for injection and infusion	Ibigen Srl Via Fossignano 2, 04011 – Aprilia (LT), Italy
4. United Kingdom (Northern Ireland) (CMS)	Rocuronium bromide 10 mg/mL solution for injection and infusion	Ibigen Srl Via Fossignano 2, 04011 – Aprilia (LT), Italy

**This leaflet was last revised in {MM/YYYY}**

<[To be completed nationally]>

**The following information is intended for medical or healthcare professionals only:**

Single use only.

Discard any unused solution.

The solution should be used immediately after opening the Ampoule/vial.

Rocuronium bromide Tamarang has been shown to be compatible with: sodium chloride 9 mg/mL (0.9%) solution, glucose 50 mg/mL (5%) solution, glucose 33 mg/mL (3.3 %) in sodium chloride 3 mg/mL (0.3%) solution, water for injections and Lactated Ringers.

Rocuronium bromide Tamarang must not be mixed with other medicinal products except those mentioned above.

Physical incompatibility has been documented for Rocuronium bromide Tamarang when added to solutions containing the following active substances: amphotericin, amoxicillin, azathioprine, cefazolin, cloxacillin, dexamethasone, diazepam, enoximone, erythromycin, famotidine, furosemide, hydrocortisone sodium succinate, insulin, intralipid, methohexital, methylprednisolone, prednisolone sodium succinate, thiopental, trimethoprim and vancomycin.

If Rocuronium bromide Tamarang is administered via the same infusion line that is also used for other medicinal products, it is important that this infusion line is adequately flushed (e.g. with sodium chloride 9 mg/mL (0.9% w/v) solution) between administration of Rocuronium bromide Tamarang and medicinal products for which incompatibility with Rocuronium bromide Tamarang has been demonstrated or for which compatibility with Rocuronium bromide Tamarang has not been established.