### **Consumer Medicine Information (CMI) summary**

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I being given Rocuronium Kabi?

Rocuronium Kabi contains the active ingredient rocuronium bromide. Rocuronium Kabi is one of a group of medicines called muscle relaxants.

Rocuronium Kabi is 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. For more information, see Section <u>1. Why am I being given ROCURONIUM KABI?</u> in the full CMI.

### 2. What should I know before I am given Rocuronium Kabi?

Do not use if you have ever had an allergic reaction to ROCURONIUM KABI or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I am given ROCURONIUM KABI? in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with ROCURONIUM KABI and affect how it works. A list of these medicines is in Section <u>3. What if I am taking other medicines?</u> in the full CMI.

### 4. How is Rocuronium Kabi given?

Rocuronium Kabi will be given by a doctor. It will not be given to you until you are asleep from the anaesthetic. It will be injected into a vein before and/or during an operation. It will be given as a single injection or continuous infusion. More instructions can be found in Section 4. How is ROCURONIUM KABI given? in the full CMI.

### 5. What should I know after being given Rocuronium Kabi?

Driving or using	• Your doctor will tell you when it is safe to drive and operate potentially dangerous machinery after
machines	you have been given Rocuronium Kabi

For more information, see Section 5. What should I know after being given ROCURONIUM KABI? in the full CMI.

### 6. Are there any side effects?

Like all medicines, Rocuronium Kabi can cause side effects, although not everybody gets them. Your doctor will discuss these with you and will explain the risks and benefits of using Rocuronium Kabi.

When you get given Rocuronium Kabi, you can have some serious side effects.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

# Rocuronium Kabi

Active ingredient: Rocuronium bromide

### **Consumer Medicine Information (CMI)**

This leaflet provides important information about using Rocuronium Kabi. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Rocuronium Kabi.

### Where to find information in this leaflet:

- 1. Why am I being given Rocuronium Kabi?
- 2. What should I know before I am given Rocuronium Kabi?
- 3. What if I am taking other medicines?
- 4. How is Rocuronium Kabi given?
- 5. What should I know after being given Rocuronium Kabi?
- 6. Are there any side effects?
- 7. Product details

### 1. Why am I being given Rocuronium KABI?

**Rocuronium Kabi contains the active ingredient rocuronium bromide.** Rocuronium Kabi is one of a group of medicines called muscle relaxants.

**Rocuronium Kabi is 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 to the muscles by impulses. Rocuronium Kabi acts by blocking these impulses so the muscles are relaxed. Because the muscles needed for breathing also become relaxed you will need help with your breathing (artificial respiration) during and after your operation until you can breathe on your own. During the operation the effect of the muscle relaxant is constantly checked and if necessary some more drug is given. At the end of the operation the effects of Rocuronium Kabi are allowed to wear off and you can start breathing on your own. Sometimes another drug is given to help speed this up. Rocuronium Kabi can also be used in Intensive Care to keep your muscles relaxed.

Rocuronium Kabi is not addictive.

# 2. What should I know before I am given ROCURONIUM KABI?

#### Warnings

If you are going to have an operation it is important that you discuss the following points with your doctor, since it can influence the way Rocuronium Kabi is given to you.

#### Do not use Rocuronium Kabi if:

- you are allergic to rocuronium bromide, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

### Check with your doctor if you:

- have or have had any other medical conditions, especially the following:
  - o an allergy to muscle relaxants
  - kidney disease
  - o liver or gallbladder disease
  - o a heart disease
  - o diseases affecting nerves or muscles
  - oedema (local or generalised swelling due to fluid)
- have any medical conditions that may affect how Rocuronium Kabi works:
  - o low potassium levels in the blood
  - $\circ \quad \ \ \, \text{high magnesium levels in the blood}$
  - low calcium levels in the blood
  - $\circ \quad \text{low levels of protein in the blood}$
  - o dehydration
  - too much acid in the blood
  - $\circ \quad$  too much carbon dioxide in the blood
  - o general ill-health
  - o overweight
  - o burns

If you are suffering from any of these conditions your doctor will take this into account when deciding the correct dose of Rocuronium Kabi for you.

- take any medicines for any other condition
- have allergies to any other medicines

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

#### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor will discuss the risks and benefits of using Rocuronium Kabi if you are pregnant or breast-feeding.

### Children / Elderly

Rocuronium Kabi can be used in children and elderly patients but your doctor should first assess your medical history.

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop. **Some medicines may interfere with ROCURONIUM KABI and affect how it works.** 

### Medicines that may increase the effect of Rocuronium Kabi include:

- anaesthetics (medicines used to make you sleep during surgery)
- long term concurrent use of corticosteroids (antiinflammatory medicines) and Rocuronium Kabi in the Intensive Care Unit
- antibiotics
- lithium (medicines used to treat bipolar disorder)
- quinidine, calcium channel blockers, betablockers and diuretics (fluid tablets) (medicines used to treat heart disease or high blood pressure)
- quinine (a medicine used to treat malaria)
- magnesium salts
- lidocaine (lignocaine) and bupivacaine (local anaesthetics)
- use of phenytoin (medicines used to treat epilepsy) during an operation

### Medicines that may reduce the effect of Rocuronium Kabi include:

 long term use of carbamazepine and phenytoin (medicines used to treat epilepsy)

## Medicines that have variable effect of Rocuronium Kabi include:

• other muscle relaxants

### Rocuronium Kabi may influence the effects of the following medicines:

• the effect of local anaesthetics (lidocaine) may be increased

You may need to use different amounts of your medicines or take different medicines. Your doctor will advise you.

If you are taking magnesium sulfate to treat toxaemia of pregnancy (preeclampsia), tell your doctor as the dose of Rocuronium Kabi may need to be reduced.

Your doctor will have a complete list of medicines that may

cause problems when used with Rocuronium Kabi.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ROCURONIUM KABI.

### 4. How is Rocuronium Kabi given?

### How much to use

The doctor will determine the dose. The usual dose is 0.6 mg rocuronium bromide per kg body weight and the effect lasts 30 to 40 minutes. During the operation your doctor will check whether Rocuronium Kabi is still working. You may be given additional doses if they are needed.

### When to use Rocuronium Kabi

- Rocuronium Kabi will be given by a doctor. It will not be given to you until you are asleep from the anaesthetic.
- It will be injected into a vein before and/or during an operation. It will be given as a single injection or continuous infusion.

### If you are given too much Rocuronium Kabi

As Rocuronium Kabi doses are carefully worked out and are given by a doctor experienced in its use, it is extremely unlikely that you will be given too much Rocuronium Kabi. However, if this does happen, your doctor will make sure that you continue breathing artificially until you can breathe on your own again.

Your doctor may speed-up your recovery by giving you a drug that reverses the effects of Rocuronium Kabi.

# 5. What should I know after being given Rocuronium Kabi?

### Driving or using machines

Be careful before you drive or use any machines or tools until you know how ROCURONIUM KABI affects you. Your doctor will tell you when it is safe to drive and operate potentially dangerous machinery after you have been given Rocuronium Kabi.

### Looking after your medicine

ROCURONIUM KABI is stored in the hospital. It is stored below 30°C until the expiry date indicated on the label.

### 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention. See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less Serious side effects	What to do
<ul> <li>flushing</li> <li>pain at injection site</li> <li>irritation at injection site</li> <li>red skin rash or itchy rash</li> </ul>	Speak to your doctor if you have any of these less serious side effects and they worry you.

### Serious side effects

Serious	side effects	What to do
Signs a	nd symptoms of	Call your
cardiovascular problems:		doctor straight
٠	fast heartbeat	away, or go
•	dizziness, light-headedness	straight to the
	(low blood pressure)	Emergency
Signs a	nd symptoms of muscle	Department at
problei	ms:	your nearest
•	muscle weakness or	hospital if you
	paralysis	notice any of
•	aching muscles or	these serious
	weakness, not caused by	side effects
	exercise	after being
Signs a	nd symptoms of lung	discharged
problei		from the
•	wheezing, coughing	hospital.
•	difficulty breathing	
Signs a	nd symptoms of allergic	
reactio	ns:	
•	rapid, shallow breathing,	
	cold, clammy skin, a rapid,	
	weak pulse, dizziness,	
	weakness and fainting	
•	swelling of the face, lips,	
	mouth, tongue or throat	
	which may cause difficulty	
	in swallowing or breathing	
•	sudden signs of allergy such	
	as rash, itching, hives on the	
	skin, swelling of the face,	
	lips, tongue or other parts	
	of the body, shortness of	
	breath, wheezing or trouble	
	breathing	
•	severe allergic coronary	
	blood vessels spasm (Kounis	
	syndrome) resulting in chest	
	pain (angina) or heart attack	
	(myocardial infarction)	
Signs a	nd symptoms of problems in	
other o		

 sudden fever with rapid heartbeat, rapid breathing

	and stiffness, pain and/or	
	weakness in your muscles	
٠	dilated pupils (mydriasis) or	
	fixed pupils	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

### **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at <u>www.tga.gov.au/safety/reporting-problems</u>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

### 7. Product details

This medicine is only available with a doctor's prescription.

### What Rocuronium Kabi contains

Active ingredient (main ingredient)	Rocuronium bromide
Other ingredients	Sodium chloride
(inactive ingredients)	Hydrochloric acid
	Sodium hydroxide
	Water for injections

No preservative has been added.

Do not take this medicine if you are allergic to any of these ingredients.

### What Rocuronium Kabi looks like

ROCURONIUM KABI is clear, colourless to pale brownishyellow solution presented in a glass vial.

ROCURONIUM KABI is available as 50 mg/5 mL in packs of 10 vials (AUST R 408636)

### Who distributes Rocuronium Kabi

Fresenius Kabi Australia Pty Limited Level 2, 2 Woodland Way Mount Kuring-gai NSW 2080 Australia Telephone: (02) 9391 5555

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