



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 170100 ROCON rocuronium bromide 50 mg/5 mL solution for injection vial

ARTG entry for Medicine Registered
Sponsor Medis Pharma Pty Ltd
Postal Address PO Box 6127, North Sydney, NSW, 2059
 Australia
ARTG Start Date 18/10/2011
Product category Medicine
Status Active
Approval area Drug Safety Evaluation Branch

Conditions

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Products

1. ROCON rocuronium bromide 50 mg/5 mL solution for injection vial

Product Type	Single Medicine Product	Effective date	19/12/2017
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Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

Adjunct to general anaesthesia to facilitate endotracheal intubation during routine induction, to provide muscle relaxation and to facilitate mechanical ventilation in adults, children and infants over 1 month of age.. Adjunct to general anaesthesia to facilitate endotracheal intubation during rapid sequence induction when suxamethonium is contraindicated, however, this has not been studied in infants and children. Rocuronium is also indicated as an adjunct in the intensive care unit (ICU) to facilitate mechanical ventilation.

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Vial	Glass Type I Clear	36 Months	Store at 2 to 8 degrees Celsius	Neither child resistant closure nor restricted flow insert	Protect from Light Do not Freeze

Pack Size/Poison information

Pack Size	Poison Schedule
vial	(S4) Prescription Only Medicine

Components

1. ROCON rocuronium bromide 50 mg/5 mL solution for injection vial

Dosage Form	Injection, solution
Route of Administration	Intravenous
Visual Identification	Clear colourless to yellowish solution in glass vial

Active Ingredients

Rocuronium bromide	50 mg
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