ESMERON® 10 MG/ML SOLUTION FOR INJECTION
Rocuronium bromide

PRESCRIBING INFORMATION
Refer to Summary of Product Characteristics (SmPC) before prescribing

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to MSD (Tel: 01992 467272).

PRESENTATION
Vials of 50 mg in 5 ml or 100 mg in 10 ml. Each ml of Esmeron contains 10 mg rocuronium bromide.

USES
An adjunct to general anaesthesia to facilitate intubation during routine sequence induction and to provide skeletal muscle relaxation, during surgery in adult and paediatric patients (from term neonates to adolescents [0 to <18 years]. Also used to facilitate intubation in adults during rapid sequence induction and as an adjunct in the ICU to facilitate intubation and mechanical ventilation.

DOSAGE AND ADMINISTRATION
For administration by or under supervision of experienced clinicians familiar with action and use of neuromuscular blocking agents (NMBAs). Administered i.v. as a bolus injection or infusion. See SmPC for compatibilities.
Dosage individualised in each patient. Taking into account method of anaesthesia and sedation, duration of surgery and expected duration of mechanical ventilation, possible interactions with other drugs and patient's condition, use of neuromuscular monitoring is recommended.

In adults - For short to long lasting surgical procedures:
Intubation: 0.6 mg/kg, Rapid sequence induction: 1.0 mg/kg (0.6mg/kg in Caesarean section), Maintenance dose: 0.15 mg/kg (reduce to 0.075 - 0.1 mg/kg for long-term inhalational anaesthesia). Continuous infusion: Loading dose 0.6 mg/kg, then infusion rate 0.3 - 0.6 mg/kg/h or under inhalational anaesthesia 0.3 - 0.4 mg/kg/h. Continuous monitoring of neuromuscular block is essential.

In Paediatrics - The recommended intubation dose during routine anaesthesia and maintenance dose are similar to those in adults. The duration of action of the single intubating dose will be longer in neonates (0-27 days) and infants (28 days-2 months) than in children (2-11 years). For continuous infusion higher infusion rates might be necessary in children. Not recommended for rapid sequence induction in paediatrics.
(See SmPC for advice for intensive care procedures, elderly and overweight patients and patients with hepatic and/or biliary tract disease and/or renal failure).

CONTRAINDICATIONS
Hypersensitivity to rocuronium, bromide ion or any of the excipients.

PRECAUTIONS
Recommended to extubate only after patient has recovered sufficiently from neuromuscular block. Geriatric patients (65 years or older) may be at increased risk for residual neuromuscular block. High rates of cross-sensitivity between NMBAs have been reported. Rocuronium may increase heart rate. It is recommended that neuromuscular transmission should be monitored throughout the use of NMBAs. For patients receiving corticosteroids and NMBAs, the period of use of the NMA should be limited as much as possible. If suxamethonium is used for intubation, administration of Esmeron should be delayed until patient has clinically recovered. Hepatic and/or biliary tract disease, renal failure, prolonged circulation time, neuromuscular disease, hypothermia and obesity may influence effects of Esmeron.

**Effect on ability to drive or use machines:** Usual precautions after a general anaesthesia should be taken.

**Use in pregnancy and lactation:** Caution should be exercised when prescribing Esmeron to pregnant women. Reduce dose if magnesium salts used. Esmeron should be given to lactating women only when benefits outweigh risks.

**Interactions:** Anaesthetics, other NMBAs, antibiotics, suxamethonium, corticosteroids, diuretics, quinidine, quinine, lithium, magnesium and certain other salts, calcium channel blocking agents, phenytoin, β-blocking agents, carbamazepine, protease inhibitors. Esmeron combined with lidocaine may result in a quicker onset of action of lidocaine. These interactions should be taken into account for paediatric patients.

**SIDE EFFECTS**

Refer to Summary of Product Characteristics for complete information on side effects. The most commonly occurring side effects include injection site pain/reaction, changes in vital signs and prolonged neuromuscular block. The most frequently reported serious side effect during post-marketing surveillance is anaphylactic and anaphylactoid reactions and associated symptoms listed below. Adverse reactions are listed under heading of frequency using the following categories: Uncommon/Rare (<1/100, >1/10 000) and Very rare (<1/10 000).

**Immune system disorders:** Very rare: Hypersensitivity, Anaphylactic shock, Anaphylactoid shock

**Nervous system disorders:** Very rare: Flaccid paralysis

**Cardiac disorders:** Uncommon/Rare: Tachycardia  
**Vascular disorders:** Uncommon/Rare: Hypotension; Very rare: Circulatory collapse and shock, Flushing

**Respiratory, thoracic and mediastinal disorders:** Very rare: Bronchospasm

**Skin and subcutaneous disorders:** Very rare: Angioneurotic oedema, Urticaria, Rash, Erythematous rash

**Musculoskeletal and connective tissue disorders:** Very rare: Muscular weakness, Steroid myopathy

**General disorders and administration site conditions:** Uncommon/Rare: Drug ineffective, Drug effect/therapeutic response decreased, Drug effect/therapeutic response increased; Very rare: Face oedema, Malignant hyperthermia

**Injury, poisoning and procedural complications:** Uncommon/Rare: Delayed recovery from anaesthesia; Very rare: Airway complication of anaesthesia

**OVERDOSE**

Patient should continue to be ventilated and sedated. In adults, sugammadex can be used for reversal of intense (profound) and deep block. An acetylcholinesterase inhibitor (e.g. neostigmine, edrophonium, pyridostigmine) or sugammadex can be used once spontaneous
recovery starts. When reversal fails ventilation must be continued until spontaneous breathing occurs.

**OTHER INFORMATION**

Dose of 0.6 mg/kg provides adequate intubation conditions within 60 seconds in nearly all patients, with clinical duration of 30-40 minutes. General muscle paralysis established within 2 minutes. With lower dosages of 0.3 – 0.45 mg/kg onset of action is slower and duration of action is shorter. With higher dosages of 2 mg/kg onset of action is faster and duration of action is longer.

**PACKAGE QUANTITIES AND BASIC NHS COST**

- 50 mg x 10 vials: £28.92
- 100 mg x 10 vials: £57.85

**PRODUCT LICENCE NUMBER**

PL 05003/0041

**MARKETING AUTHORISATION HOLDER**

N V Organon, 5340 BH, Oss, The Netherlands

**POM** Date of review of prescribing information: September 2015

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