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 or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to MSD (Tel: 01992 467272), UK.

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 tracheal 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 tracheal 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. Individualise dosage in each patient based on method of anaesthesia and sedation, duration of surgery, expected duration of mechanical ventilation, possible interactions with other drugs and patient's condition. Neuromuscular monitoring is recommended.

Adults - For short to long lasting surgical procedures:
Tracheal 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.

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.

(See SmPC for advice for intensive care procedures, elderly, overweight patients and patients with hepatic and/or biliary tract disease and/or renal failure).

CONTRA-INDICATIONS
Hypersensitivity to rocuronium, bromide ion or any of the excipients.

PRECAUTIONS
Since Esmeron causes paralysis of the respiratory muscles ventilatory support is mandatory for patients until adequate spontaneous respiration is restored. 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. Exclude hypersensitivity to other NMBAs before administering Esmeron if possible. Rocuronium may increase heart rate. Monitor neuromuscular transmission throughout the use of NMBAs. Limit the period of use of NMBA in patients receiving corticosteroids, as myopathy has been reported with long term concomitant use. If suxamethonium is used for intubation, delay administration of Esmeron until patient has clinically recovered. Rare cases of malignant hyperthermia associated with administration of Esmeron have been observed during post-marketing surveillance. The causal association is unknown. Hepatic and/or biliary tract disease, renal failure, prolonged circulation time, neuromuscular disease, hypothermia and obesity may influence effects of Esmeron.

Interactions: The following drugs have been shown to influence the magnitude and/or duration of action of NMBAs: 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.

**Use in pregnancy and lactation:**

*Pregnancy:* Exercise caution when prescribing Esmeron to pregnant women. Reduce dose if magnesium salts used.

*Lactation:* Use only when benefits outweigh risks. After single dose administration it is recommended to abstain from breastfeeding for five elimination half-lives of rocuronium, i.e. for about 6 hours.

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

**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: dace oedema.

**Injury, poisoning and procedural complications:** Uncommon/Rare: delayed recovery from anaesthesia; Very rare: dirway 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

**Marketing Authorisation Number**

PL 05003/0041

**Marketing Authorisation Holder**

N V Organon, 5340 BH, Oss, The Netherlands

**Legal Category:** POM

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