

**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](http://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 UK (Tel: 01992 467272). By clicking the above link you will leave the MSD website and be taken to the MHRA website.**

**PRESENTATION**

Vials of 50 mg in 5 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, Adequate intubation conditions are established within 60 seconds in most patients. Caesarean section: 0.6mg/kg, Intubate the patient 90 seconds after administration if 0.6 mg/kg is used for rapid sequence induction. Maintenance dose: 0.15 mg/kg (reduce to 0.075 - 0.1 mg/kg for long-term inhalational anaesthesia). Administer maintenance dose when twitch height has recovered to 25% of control or when 2 to 3 responses to train of four stimulation are present. Continuous infusion: Loading dose: 0.6 mg/kg. Start administration infusion when neuromuscular block starts to recover. Adjust rate to maintain twitch response at 10% of control

twitch height or to maintain 1 to 2 responses to train of four stimulation. To maintain block, in adults under intravenous anaesthesia, usual dose ranges from 0.3-0.6 mg/kg/h and under inhalational anaesthesia from 0.3-0.4 mg/kg/h. Monitor patients continuously.

**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, the infusion rates are similar to adults, although higher infusion rates might be necessary in children aged 2-11 years. Not recommended for rapid sequence induction.

**Special populations**

Esmeron is not recommended for the facilitation of mechanical ventilation in the intensive care in paediatric and geriatric patients due to a lack of data on safety and efficacy.

(See SmPC for advice for intensive care procedures, higher doses, 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. Only use when essential in susceptible patients. Rocuronium may increase heart rate. In general, following long term use of NMBAs in the ICU, prolonged paralysis and/or skeletal muscle weakness has been noted, therefore monitoring neuromuscular transmission throughout the use of NMBAs is recommended. Ensure patients receive adequate analgesia and sedation. 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. Be aware of early symptoms, confirmatory diagnosis and treatment of malignant hyperthermia prior to the start of anaesthesia. Hepatic and/or biliary tract disease, renal failure, prolonged circulation time, neuromuscular disease, hypothermia, obesity, burns, hypokalaemia hypermagnesaemia, hypocalcaemia hypoproteinaemia, dehydration, acidosis, hypercapnia, cachexia and severe electrolyte disturbances may influence effects of Esmeron.

**Interactions:** The following drugs have been shown to influence the magnitude and/or duration of action of non-depolarising NMBAs: Anaesthetics, other NMBAs, antibiotics, suxamethonium, corticosteroids, diuretics, quinidine, quinine, lithium and magnesium salts, calcium channel blocking agents, phenytoin,  $\beta$ -blocking agents, local anaesthetics, carbamazepine, calcium chloride, potassium chloride, protease inhibitors. Recurarisation has been reported after post-operative administration of some antibiotics and certain diuretics. 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. 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; Not known: Kounis syndrome.

**Vascular disorders:** Uncommon/Rare: hypotension; Very rare: circulatory collapse and shock, flushing.

**Respiratory, thoracic and mediastinal disorders:** Very rare: bronchospasm.

**Skin and subcutaneous tissue 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.

**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.

***Incompatibilities***

Esmeron must not be mixed with other products except those stated in SmPC. Physical incompatibility has been reported with: amphotericin, amoxicillin, azathioprine, cefazolin, cloxacillin, dexamethasone, diazepam, enoximone, erythromycin, famotidine, furosemide, hydrocortisone sodium succinate, insulin, intralipid, methylprednisolone, prednisolone sodium succinate,

methohexital, thiopental, trimethoprim and vancomycin.

**PACKAGE QUANTITIES AND BASIC NHS COST**

50 mg x 10 vials: £28.92

**PRODUCT LICENCE NUMBER**

PL 05003/0041

**MARKETING AUTHORISATION HOLDER**

N V Organon, 5340 BH, Oss, The Netherlands

**Legal Category: POM**

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