CURON

CURON 50 mg/5 ml IV - vial containing solution for IV injection, 5 vials

COMPOSITION: Each ml of CURON contains 10 mg rocuronium bromide; and as inactive ingredients, sodium chloride, sodium acetate acetic acid and water for injection.

PHARMACOLOGICAL PROPERTIES: CURON (rocuronium bromide) is a non-polarizing neuromuscular blocking agent with a rapid onset of action and a median-effect that has all the characteristic pharmacological effects of this class of drugs (curariform). It shows its effect by competing for the nicotinic colineceptors in motor end plaque. This effect is antagonized by acetylcholinesterase inhibitors like neostigmin, edrophonium and pyridostigmin. The required dose for 90% suppression of the twitch-response of thumb due to stimulation of the ulnar nerve during intravenous anesthesia is approximately 0.3 mg/kg rocuronium bromide. The clinical duration obtained with 0.6 mg/kg rocuronium bromide (the period for spontaneous recovery of 25% of the control twitch peak) is 30-40 minutes. Following intravenous administration of a 0.6 mg/kg rocuronium bromide dosage, adequate intubation conditions were obtained in 60 seconds in nearly all patients. In normal adults, mean elimination half life is 73 (66-80) hours. After about 9 days of injection of a rocuronium bromide dosage, mean elimination rates are 47% from urine and 43% from feces.

INDICATIONS: CURON is indicated as an adjunct to general anesthesia to facilitate tracheal intubation during routine and rapid sequence induction, and to provide skeletal muscle relaxation during surgery. CURON is also indicated as an adjunct in the intensive care unit (ICU) to facilitate intubation and mechanical ventilation.

CONTRAINDICATIONS: Hypersensitivity to rocuronium or its bromide ion or any of the inactive products.

WARNINGS AND PRECAUTIONS: Since CURON causes paralysis of the respiratory muscles, ventilatory support should be supported in patients receiving this drug until respiration is recovered to a sufficient level. When used as part of the rapid sequence induction technic, emergence of intubation problems should be expected. Residuel curarization has been reported with CURON. To prevent complications due to residuel curarization, it is recommended that intubation is performed only when the patient is sufficiently awake from neuromuscular blokage. Since there are reported cases of anaphylactic reactions particularly to neuromuscular blocking agents, special precautions are required because of reports related to cross-allergic reactions with neuromuscular blocking agents. In general, prolonged paralysis and/or atrophy of the skeletal muscles are observed following prolonged use of muscle relexants in intensive care units. If succinylcholine is used for intubation, CURON administration should be postponed until patient recovers from the neuromuscular blockage clinically induced by succinylcholine. Since rocuronium is eliminated by urine and bile, it should be used with caution in patients with clinically important hepatic and/or biliary tract disease and/or renal failure. Therefore, severe electrolyte deteriorations, blood pH level abnormalities or dehydration should be corrected as much as possible. **Effects on driving and machine use:** Common precautions taken following CURON use during general anesthesia should also be applied for ambulatory patients. **Pregnancy category is C.** In patients undergoing Cesarean section, CURON can be used as part of a rapid sequence induction technique, provided no intubation difficulties are anticipated and a sufficient dose of anesthetic agent is administered or following succinylcholine facilitated intubation.

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PROD INFO

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SIDE EFFECTS / ADVERSE EFFECTS: The most commonly occurring adverse drug reactions include injection site pain/reaction, changes in vital signs and prolonged neuromuscular block. The most frequently reported serious adverse drug reactions during postmarketing surveillance is 'anaphylactic and anaphylactoid reactions' and associated symptoms.

DRUG INTERACTIONS: Drugs that potentiate the effect of CURON: Prolonged concomitant administration with halogenized volatile anesthetic agents, after intubation with succinylcholine, corticosteroids. Other interacting agents: antibiotics: aminoglycosides, lincosamide and polypeptide antibiotics, acilamino-penicilline antibioticsi, diuretics, quinidine and its isomer quinine, magnesium saltaı, calcium channel blocker agents, lithium salts, local anesthetics (lidocain intravenous bupivacaine epidural) phenytoin or bolus administration of 13-blocking agents. Agents that decrease its effect: phenytoinine or carbamazepine, protease inhibitors (gabexate, ulinastatin). Variable effect: Other non-depolarisating neuromuscular blocker agents, succinylcholine.

DOSAGE AND ADMINISTRATION: CURON should only be administered by or under the surveillance of experienced physicians who are familiar with the effects and use of these drugs. During routine anesthesia, the standard intubation dose is 0.6 mg/kg rocuronium bromide. When there is a need for administration of higher doses in patients, as long as there are no adverse cardiovascular effects, initial rocuronium bromide doses upto 2 mg/kg has been administered during surgery. The recommended maintenance dosage is 0.15 mg/kg rocuronium bromide. In adult patients under intravenous anesthesia, the infusion rate required to preserve the neuromuscular blockage at this level is 0.3-0.6 mg/kg/hour and under general anesthesia, the infusion rate is 0.3-0.4 mg/kg/hour. The recommended intubation dosage and rate is the same as in adults in infants (28 days-23 months), children (2-11 years) and adolescents (12-18 years) under routine anesthesia. In geriatric patients and in patients with liver and/or biliary disease and /or renal failure, the standard intubation dosage during routine anesthesia is 0.6 mg/kg rocuronium bromide. In these patients the recommended maintenance dosage is 0.075-0.1 mg/kg rocuronium bromide and infusion rate is 0.3-0.4 mg/kg/hour.

STORAGE CONDITIONS: CURON should be kept in a dark place at 2-8°C temperature. Since the product contains no additives, it should be used as soon as the vial is opened. The product cannot be kept in the refrigerator once the vial is opened.

AVAILABLE FORMS: CURON 50 mg/5 ml vials containing solution for IV injection are in 5-vial packages. It is sold under prescription. Please contact our company for further details.

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PRODUCT INFO