Blok-L

Blok-L IV 4 mg injection, 1 vial + 1 diluent ampoule
Blok-L IV 10 mg injection, 1 ampoule + 1 diluent ampoule

COMPOSITION: Containing lyophilized powder for Blok-L 10 mg IV injection contains 10 mg vecuronium bromide as a mass. Each ampoule containing lyophilized powder for Blok-L 4 mg IV injection contains 4 mg vecuronium bromide as a mass.

PHARMACOLOGICAL PROPERTIES: Vecuronium bromide is a medium-effective neuromuscular blocker and shows its effect by binding to the motor end-plaque cholinergic receptors in muscles and inhibiting the effects of acetylcholine. The duration of effect of vecuronium is 1/3 of pancuronium: it is the same or slightly shorter than that of atracurium. With 0.05 mg/kg dose (ED-95), the duration of effect of vecuronium (90-95 % correction) is approximately 30 minutes; however, with 0.10 mg/kg doses (2XED-95) this period is increased to about 45 minutes. In clinic doses it is 60-80% bound to plasma proteins. Elimination half-life is about 65-75 minutes. In the later months of pregnancy half life can be shorter and is about 35-40 minutes. Vecuronium is eliminated by the hepato-biliary system.

INDICATIONS: Blok-L is used in general anesthesia and in surgical or mechanical ventilation as an aid to anesthesia to facilitate endotracheal intubation and to provide relaxation of the skeltal muscle.

CONTRAINDICATIONS: Blok-L should not be used in patients hypersensitive to vecuronium bromide.

WARNINGS AND PRECAUTIONS: Blok-L should be administered under the supervision of an experienced physician or medical person who is familiar with the subject and who knows the activity mechanism of the product and potential complications, precautions to be taken and treatment methods. This drug should not be used in environments where intubation, artificial ventilation, oxygen therapy, peripheral nerve stimulator and access to antagonists to be used are not available. Ventilation should be supported during neuromuscular blockage. Some clinical conditions listed below can potentiate or antagonize neuromuscular blockage. Potentiation of neuromuscular blockage: Electrolyte abnormalities, serious hyponatremia, serious hypocalcemia, serious hypopotasemia, hypermagnesemia, neuromuscular diseases, acidosis, acute intermittant porfiri, renal failure, hepatic failure. Antagonism of neuromuscular blockage: Alkalosis, hypercalcemia, demyelinizating, Lesions, peripheral neuropathy, diabetes mellitus. Low-dose vecuronium can be effective in individuals with myasthenia gravis or in myasthenic patients. Therefore, testing with very low doses before administration is recommended. Over-sensitivity can be seen in patients with Eaton-Lambert syndrome. In burn patients (more than 30% of the body) resistance can be seen for a period of 5-70 days after the accident. Resistance can also be seen in muscle trauma, denervation, immobilization and infection conditions. Does not prevent bradycardia caused by anesthetics/vagal stimulation. Use in pregnancy: **Pregnancy category is C.**

SIDE EFFECTS / ADVERSE EFFECTS: Generally, the side effect produced by all non-polarizing neuromuscular blocker agents is more-than-required prolongation of the pharmacokinetic effect of the drug used. This results in side effects varying in severity from weakening of the striated muscle to respiratory failure and apnea. In vecuronium administration, hypersensitivity reactions such as. bronchospasm, hypotension, tachycardia, urticaria and erythema can be observed rarely. It should be considered that cross allergic reactions develop between non-depolarizing neuromuscular blocker agents. Bradycardia, circulatory collapse, edema and flushing can be seen.

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PROD INFO

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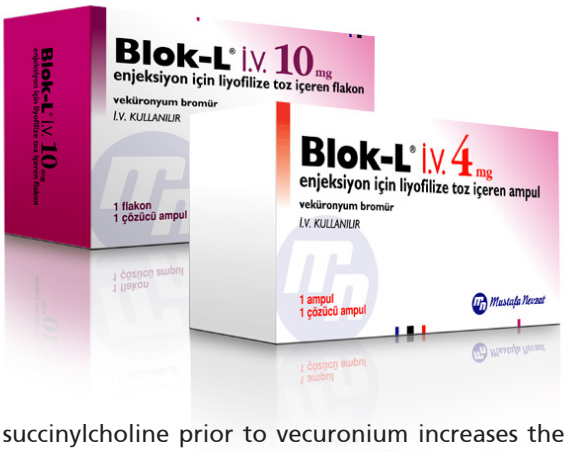

DRUG INTERACTIONS: Administration of succinylcholine prior to vecuronium increases the blocking effect and duration of the effect of vecuronium. Inhalation anesthetics and other anesthetics: Inhalation anesthetics and other anesthetics such as enfluran, isofluran and halotan can increase the neuromuscular blocking effect of vecuronium. Aminoglycosides, antibiotics such as colistin, polymixin-B, etracyclines, macrolides, clindamycin, quinolons, vancomycin and bacitracin are associated with paralysis at various levels and concomitant administration with vecuronium can result in unexpected prolongation of neuromuscular blockage. Beta-blockers, calcium canal blockers, imipenem, ketamin, lidocain, loop diuretics (furosemide), magnesium sulphate and procainamide can also increase the effect of vecuronium. Vecuronium administration concomitantly with prolonged use of high-dose corticosteroids can increase the risk for myopathy.

DOSAGE AND ADMINISTRATION: Blok-L ampoule should only be administered intravenously. As with the other neuromuscular blocking agents, the dose of vecuronium bromide, the active ingredient of Blok-L, should be individually adjusted according to the patient's condition and the type of surgery to be performed. Dosage and administration in adults: Generally, intraoperative starting bolus dose of 0.08-0.10 mg/kg is recommended in adult patients. In non-emergency intubations, this dose is administered in 2.5-3 minutes. Following this dose, in prolonged surgical interventions, a maintenance dose of 0.010-0.015 mg/kg should be administered. Continuous infusion: Approximately 20-40 minutes after the first intubation dose of 80-100 mcg/kg vecuronium bromide, continuous infusion should be given at a dose of 1 mcg/kg/min. The mean infusion rate can be 0.8-1.2 mcg/kg/min. In infants aged 5 months-1 year adult dosage is recommended. Administration method: Blok-L vial and ampoule is administered only by intravenous route and should be used after reconstitution. Blok-L vial and ampoule can be given in 5% glucose/water, 5% glucose 0.9% NaCl, lactated ringer solution. Unused portions of the infusion solutions should be discarded immediately.

STORAGE CONDITIONS: It should be kept in room temperature <25°C protected from light. Following reconstitution, it is stable for 24 hours in room temperature under day light.

AVAILABLE FORMS: There are 1 vial containing 10 mg vecuronium bromide and 10 mL diluent ampoule in the package of BLOK-L 10 mg IV vial containing lyophilized powder for injection. There are 1 ampoule containing 4 mg vecuronium bromide and 1 mL diluent ampoule in the package of BLOK-L 4 mg IV ampoule containing lyophilized powder for injection.

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