Atracurium Besylate (atracurium besylate) - Drug Summary

Bedford Laboratories

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Atracurium
(atracurium besylate)

THERAPEUTIC CLASS

Skeletal muscle relaxant (nondepolarizing)

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Adjunct to General Anesthesia

To facilitate endotracheal intubation and to provide skeletal muscle relaxation during surgery or mechanical ventilation

Intubation and Maint of Neuromuscular Block:
Initial: 0.4-0.5mg/kg (1.7-2.2 x ED_{95}) IV bolus inj

Under Isoflurane/Enflurane Anesthesia:
The same initial dose may be used for intubation prior to administration of these inhalation agents; however, if atracurium is 1st administered under steady-state of isoflurane or enflurane, the initial atracurium dose should be reduced by approx one-third (0.25-0.35mg/kg), to adjust for the potentiating effects of these anesthetic agents

Under Halothane Anesthesia:
Halothane has only a marginal (approx 20%) potentiating effect on atracurium; smaller dosage reductions may be considered

Maint During Prolonged Surgical Procedures:
0.08-0.1mg/kg; 1st maint dose will generally be required 20-45 min after initial atracurium inj, but the need for maint doses should be determined by clinical criteria

Maint doses may be administered at relatively regular intervals, ranging approx from 15-25 min under balanced anesthesia, slightly longer under isoflurane or enflurane; higher atracurium doses (up to 0.2mg/kg) permit maint dosing at longer intervals

Continuous Infusion (In the Operating Room/ICU):
Administer for maint of neuromuscular block during extended surgical procedures; initiate infusion only after early evidence of spontaneous recovery from the initial bolus dose

Infusion Rate: 9-10mcg/kg/min may be required to rapidly counteract the spontaneous recovery of neuromuscular function, then 5-9mcg/kg/min should be adequate to maintain continuous neuromuscular block in most patients under balanced anesthesia

Occasional patients may require infusion rates as low as 2mcg/kg/min or as high as 15mcg/kg/min

Consider reduction in the infusion rate of atracurium for patients receiving inhalation anesthesia; the rate of atracurium infusion should be reduced by approx one-third in the presence of steady-state enflurane or isoflurane anesthesia and smaller reductions should be considered in the presence of halothane

ICU: An infusion rate of 11-13mcg/kg/min (range: 4.5-29.5) should provide adequate neuromuscular block

Following recovery from neuromuscular block, readministration of a bolus dose may be necessary to quickly reestablish neuromuscular block prior to reinstitution of the infusion

Refer to PI for infusion rate tables

PEDIATRIC DOSAGE & INDICATIONS

Adjunct to General Anesthesia

To facilitate endotracheal intubation and to provide skeletal muscle relaxation during surgery or mechanical ventilation

1 Month-2 Years:
Under Halothane Anesthesia:
Initial: 0.3-0.4mg/kg IV bolus inj
Maint: May be required w/ slightly greater frequency than in adults

≥2 Years:
Continuous Infusion (In the Operating Room/ICU):
Administer for maint of neuromuscular block during extended surgical procedures; initiate infusion only after early evidence of spontaneous recovery from the initial bolus dose

Infusion Rate: 9-10mcg/kg/min may be required to rapidly counteract the spontaneous recovery of neuromuscular function, then 5-9mcg/kg/min should be adequate to maintain continuous neuromuscular block in most patients under balanced anesthesia

Occasional patients may require infusion rates as low as 2mcg/kg/min or as high as 15mcg/kg/min

Consider reduction in the infusion rate of atracurium for patients receiving inhalation anesthesia; the rate of atracurium infusion should be reduced by approx one-third in the presence of steady-state enflurane or isoflurane anesthesia and smaller reductions should be considered in the presence of halothane

ICU: Limited information suggests that infusion rates required for pediatric patients in the ICU may be higher than in adult patients

Following recovery from neuromuscular block, readministration of a bolus dose may be necessary to quickly reestablish neuromuscular block prior to reinstitution of the infusion

Refer to PI for infusion rate tables

DOSING CONSIDERATIONS

Concomitant Medications
Adults:
Following Succinylcholine Use for Intubation Under Balanced Anesthesia:
Initial: 0.3-0.4mg/kg; further reductions may be desirable w/ the use of potent inhalation anesthetics
The patient should be permitted to recover from the effects of succinylcholine prior to atracurium administration

Other Important Considerations
Adults and Pediatrics:
Significant Cardiovascular Disease or Any History Suggesting a Greater Risk of Histamine Release:
Initial: 0.3-0.4mg/kg, given slowly or in divided doses over 1 min

Dosage reductions must be considered also in patients w/ neuromuscular disease, severe electrolyte disorders, or carcinomatosis in which potentiation of neuromuscular block or difficulties w/ reversal have been demonstrated

Continuous Infusion:
Patients Undergoing Cardiopulmonary Bypass w/ Induced Hypothermia: The rate of infusion required to maintain adequate surgical relaxation is approx 1/2 the rate required during normothermia

ADMINISTRATION

IV route

Do not administer before unconsciousness has been induced
Do not mix in the same syringe, or administer simultaneously through the same needle, w/ alkaline sol (eg, barbiturate sol)

Compatibility
Infusion sol may be prepared by admixing atracurium besylate inj w/ an appropriate diluent such as:
D5 inj
0.9% NaCl inj
D5 and 0.9% NaCl inj

Infusion sol should be used w/in 24 hrs of preparation; discard unused sol
Sol containing 0.2mg/mL or 0.5mg/mL atracurium besylate in the above diluents may be stored either under refrigeration or at room temperature for 24 hrs

Do not use lactated Ringer's inj as a diluent in preparing sol of atracurium besylate inj for infusion

HOW SUPPLIED

Inj: 10mg/mL [5mL, 10mL]

CONTRAINDICATIONS

Hypersensitivity to atracurium besylate or benzyl alcohol (10mL vial).

WARNINGS/PRECAUTIONS

Should be used only by those skilled in airway management and respiratory support; adequacy of respiration must be assured through assisted or controlled ventilation and anticholinesterase reversal agents should be immediately available. Do not administer before unconsciousness has been induced. Multiple-dose vials (10mL) contain benzyl alcohol; associated with an increased incidence of neurological and other complications (sometimes fatal) in neonates. Severe anaphylactic reactions reported. Caution in patients who have had previous anaphylactic reactions to other neuromuscular blocking agents; cross-reactivity reported. Caution in patients in whom substantial histamine release would be especially hazardous (eg, with clinically significant CVD) and in patients with any history (eg, severe anaphylactoid reactions, asthma) suggesting a greater risk of histamine release. Bradycardia during anesthesia may be more common than with other muscle relaxants. May have profound effects in patients with myasthenia gravis, Eaton-Lambert syndrome, or other neuromuscular diseases; the use of a peripheral nerve stimulator is especially important for assessing neuromuscular block in these patients. Monitor for malignant hyperthermia (MH). Resistance may develop in burn patients; may require

increased doses. Seizures in ICU patients reported rarely. Whenever the use of therapy is contemplated in the ICU, continuously monitor neuromuscular transmission with the help of a nerve stimulator; do not give additional doses or any other neuromuscular blocking agents before there is a definite response to T_1 or to the 1st twitch. D/C infusion administration until a response returns if no response is elicited. Caution in patients with severe electrolyte disorders or carcinomatosis.

ADVERSE REACTIONS

Skin flushing, decreased mean arterial pressure, increased HR.

DRUG INTERACTIONS

See Dosage. Enflurane, isoflurane, halothane, lithium, Mg^{2+} salts, procainamide, quinidine, and certain antibiotics (eg, aminoglycosides, polymyxins), may enhance neuromuscular blocking action. Consider possibility of synergistic or antagonist effect if other muscle relaxants are used during the same procedure. Prior administration of succinylcholine may quicken onset and increase depth of neuromuscular block; do not administer until patient has recovered from succinylcholine-induced neuromuscular block.

PREGNANCY AND LACTATION

Category C, caution in nursing.

MECHANISM OF ACTION

Nondepolarizing skeletal muscle relaxant; antagonizes the neurotransmitter action of acetylcholine by binding competitively with cholinergic receptor sites on the motor end plate.

PHARMACOKINETICS

Distribution: Crosses the placenta. **Metabolism:** Ester hydrolysis and Hofmann elimination. **Elimination:** Bile, urine; $T_{1/2}$=20 min.

ASSESSMENT

Assess for hypersensitivity to drug or to benzyl alcohol, previous anaphylactic reactions to other neuromuscular blocking agents, histamine sensitive individuals, myasthenia gravis, neuromuscular diseases, severe electrolyte disorders, carcinomatosis, burns, pregnancy/nursing status, and possible drug interactions.

MONITORING

Monitor for signs/symptoms of anaphylactic reactions, seizures in ICU patients, MH, and other adverse reactions. Monitor neuromuscular transmission continuously with the help of a nerve stimulator.

PATIENT COUNSELING

Inform about the benefits and risks of therapy. Inform that severe anaphylactic reactions may occur.

STORAGE

2-8°C (36-46°F). Do not freeze. Upon removal from refrigeration to 25°C (77°F), use within 14 days even if rerefrigerated.

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