

# SIZE : 78MMX184MM



## Atracurium Besylate Injection IP 10 mg

### Atracurium Besylate Injection Prescribing Information

#### Package insert/ product label

**Dosage form:** Injection, solution

**Drug class:** Neuromuscular blocking agents

#### Atracurium Besylate Injection Description

Atracurium Besylate is an intermediate-duration, nondepolarizing, skeletal muscle relaxant for intravenous administration. Atracurium Besylate is designated as 2-(2-(2-Carboxyethyl)-1,2, 3, 4-tetrahydro-6,7-dimethoxy-2-methyl-1-veratrylisoquinolinium benzenesulfonate, pentamethylene ester. It has a molecular weight of 1,243.49, and its molecular formula is C65H82N2O18S2.

#### Atracurium Besylate Injection - Clinical Pharmacology

Atracurium besylate is a nondepolarizing skeletal muscle relaxant. Nondepolarizing agents antagonize the neurotransmitter action of acetylcholine by binding competitively with cholinergic receptor sites on the motor end-plate. This antagonism is inhibited, and neuromuscular block reversed, by acetylcholinesterase inhibitors such as neostigmine, edrophonium, and pyridostigmine.

#### Indications and Usage for Atracurium Besylate Injection

Atracurium Besylate Injection, is indicated, as an adjunct to general anesthesia, to facilitate endotracheal intubation and to provide skeletal muscle relaxation during surgery or mechanical ventilation.

#### Warnings

ATRACURIUM SHOULD BE USED ONLY BY THOSE SKILLED IN AIRWAY MANAGEMENT AND RESPIRATORY SUPPORT. EQUIPMENT AND PERSONNEL MUST BE IMMEDIATELY AVAILABLE FOR ENDOTRACHEAL INTUBATION AND SUPPORT OF VENTILATION, INCLUDING ADMINISTRATION OF POSITIVE PRESSURE OXYGEN. ADEQUACY OF RESPIRATION MUST BE ASSURED THROUGH ASSISTED OR CONTROLLED VENTILATION. ANTICHOLINESTERASE REVERSAL AGENTS SHOULD BE IMMEDIATELY AVAILABLE.

DO NOT GIVE ATRACURIUM BESYLATE BY INTRAMUSCULAR ADMINISTRATION.

#### Precautions

Since allergic cross-reactivity has been reported in this class, request information from your patients about previous anaphylactic reactions to other neuromuscular blocking agents. In addition, inform your patients that severe anaphylactic reactions to neuromuscular blocking agents, including atracurium besylate have been reported.

#### Long-Term Use in Intensive Care Unit (ICU)

When there is a need for long-term mechanical ventilation, the benefits-to-risk ratio of neuromuscular block must be considered. The long-term (1 to 10 days) infusion of atracurium besylate during mechanical ventilation in the ICU has been evaluated in several studies. Average infusion rates of 11 to 13 mcg/kg per minute (range: 4.5 to 29.5) were required to achieve adequate neuromuscular block. These data suggest that there is wide interpatient variability in dosage requirements. In addition, these studies have shown that dosage requirements may decrease or increase with time. Following discontinuation of infusion of atracurium besylate in these ICU studies, spontaneous recovery of four twitches in a train-of-four occurred in an average of approximately 30 minutes (range: 15 to 75 minutes) and spontaneous recovery to a train-of-four ratio >75% (the ratio of height of the fourth to the first twitch in a train-of-four) occurred in an average of approximately 60 minutes (range: 32 to 108 minutes).

#### Labor and Delivery

It is not known whether muscle relaxants administered during vaginal delivery have immediate or delayed adverse effects on the fetus or increase the likelihood that resuscitation of the newborn will be necessary. The possibility that forceps delivery will be necessary may increase.

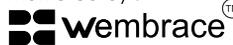
Atracurium besylate (0.3 mg/kg) has been administered to 26 pregnant women during delivery by cesarean section. No harmful effects were attributable to atracurium in any of the neonates, although small amounts of atracurium were shown to cross the placental barrier. The possibility of respiratory depression in the neonate should always be considered following cesarean section during which a neuromuscular blocking agent has been administered. In patients receiving magnesium sulfate, the reversal of neuromuscular block may be unsatisfactory and the dose of atracurium besylate should be lowered as indicated.

#### Pediatric Use

Safety and effectiveness in pediatric patients below the age of 1 month have not been established.

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