



HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use CISATRACURUM BESYLATE INJECTION safely and effectively. See full prescribing information for CISATRACURUM BESYLATE INJECTION.

CISATRACURUM BESYLATE Injection, for Intravenous use

Initial U.S. Approval: 1995

INDICATIONS AND USAGE

- Cisatracurium besylate injection is a nondepolarizing neuromuscular blocker indicated:
 - as an adjunct to general anesthesia to facilitate tracheal intubation in adults and in pediatric patients 1 month to 12 years of age (1)
 - to skeletal muscle relaxation during surgery in adults and in pediatric patients 2 to 12 years of age as a bolus or infusion maintenance (1)
 - for mechanical ventilation in the ICU in adults (1)

Limitations of Use

Cisatracurium besylate injection is not recommended for rapid sequence endotracheal intubation due to the time required for its onset of action (1).

DOSAGE AND ADMINISTRATION

Store Cisatracurium besylate injection with the cap and ferule intact and in a manner that minimizes the possibility of selecting the wrong product (2.1).

Administer intravenously only or under the supervision of experienced clinicians familiar with drug's actions and possible adverse effects (2.1).

Use only for patients and facilities for resuscitation and life support, and a cisatracurium besylate antagonist are immediately available (2.1).

Use a peripheral nerve stimulator to determine adequacy of blockade (e.g., need for additional doses), minimize risk of over-blockade, and determine if a patient has recovered sufficiently to permit extubation, both depolarizing and non-depolarizing (4, 5.4).

Risk of Seizure: Monitor level of neuromuscular blockade during long-term administration to limit exposure to toxic metabolites (5.3).

Hypotension: Reduce dose and Administer Serum: Hypotension is a reaction to cisatracurium besylate injection, both depolarizing and non-depolarizing (4, 5.4).

Bradycardia: Monitor heart rate and blood pressure during surgery in adults and in pediatric patients 2 to 12 years of age as a bolus or infusion maintenance (1).

Respiratory: Monitor oxygen saturation, end-tidal CO₂, and arterial blood gases during surgery in adults and in pediatric patients 2 to 12 years of age as a bolus or infusion maintenance (1).

Continuous infusion rates (2.6).

Preparation instructions (2.7).

Drug compatibility (2.8).

DOSAGE FORMS AND STRENGTHS

Injection:

- 10 mg/mL (2 mg/mL) single-dose vials (3)
- 20 mg/mL (2 mg/mL) and benzyl alcohol as a preservative in multiple-dose vials (3)
- 200 mg/20 mL (10 mg/mL) in single-dose vials (3)

CONTRAINDICATIONS

- Known hypersensitivity to cisatracurium (4).

WARNINGS AND PRECAUTIONS

- Residual Paralysis:** Patients with neuromuscular diseases are at higher risk. Use a lower initial bolus dose and consider using a peripheral nerve stimulator (2.1, 2.2).
- Benzyl Alcohol:** Do not combine benzyl alcohol from all sources when the 10 mL multiple-dose vials are used (2.1).
- Risk of Seizure:** Monitor level of neuromuscular blockade during long-term administration to limit exposure to toxic metabolites (5.3).

Hypotension: Reduce dose and Administer Serum: Hypotension is a reaction to cisatracurium besylate injection, both depolarizing and non-depolarizing (4, 5.4).

Bradycardia: Monitor heart rate and blood pressure during surgery in adults and in pediatric patients 2 to 12 years of age as a bolus or infusion maintenance (1).

Respiratory: Monitor oxygen saturation, end-tidal CO₂, and arterial blood gases during surgery in adults and in pediatric patients 2 to 12 years of age as a bolus or infusion maintenance (1).

Continuous infusion rates: 600 mg/h to 1,200 mg/h (2.6).

Preparation instructions: 2.7.

Drug compatibility: 2.8.

ADVERSE REACTIONS

The most common adverse reactions (0.1% to 0.4%) were bradycardia, hypotension, flushing, bronchospasm, and rash (6.1).

To report SUSPECTED ADVERSE REACTIONS, contact Cephalon Sciences Limited at 1-800-978-6111 or FDA at 1-800-FDA-1068 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- Succinylcholine:** May decrease time to onset of maximum neuromuscular blockade (7.1).

Inhalational anesthetics, antibiotics, local anesthetics, magnesium salts, procainamide, lithium, quinidine: May potentiate or prolong neuromuscular blockade action of cisatracurium besylate. Use peripheral nerve stimulator and monitor clinical signs of neuromuscular blockade (5.8, 7.1).

Hydrochloric Acid and Antacids: Serum: Hypotension is a reaction to cisatracurium besylate injection, both depolarizing and non-depolarizing (4, 5.4).

Antacids: Monitor duration of neuromuscular blockade. Use peripheral nerve stimulator and monitor clinical signs of neuromuscular blockade (5.9, 7.1).

USE IN SPECIFIC POPULATIONS

- Patients with Hemiparesis or Paraparesis:** Perform neuromuscular monitoring on non-paralized limb (8.9).

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