Cisatracurium besylate injection is for intravenous use only.

Minimize risk of overdosage or underdosage.

There have been reports of wheezing, laryngospasm, bronchospasm, rash (multiple-dose vials contain 9 mg of benzyl alcohol per mL) and other drugs containing benzyl alcohol. The minimum amount of benzyl alcohol at which serious adverse reactions may occur is not known.

Edrophonium: Administration of 1 mg/kg of edrophonium at approximately 25% recovery from neuromuscular blockade (range: 16% to 30%) produced 95% recovery and a T4:T1 ratio ≥ 70% in an average of 3 minutes.

Support ventilation until adequate spontaneous ventilation has resumed.

Intravenous administration of cisatracurium besylate injection results in paralysis, which may lead to respiratory arrest and death, a progression that may be more likely to occur in a patient for whom it is not intended. Confirm that all personnel and facilities for resuscitation and life support (tracheal intubation, artificial ventilation, oxygen therapy) are immediately available.

Cisatracurium besylate injection doses between 0.15 and 0.2 mg/kg were evaluated in 240 adults. Maximum neuromuscular blockade generally occurred within 4 minutes for this dose range.

Neuromuscular blockade was monitored by the train-of-four (TOF) and the TOF ratio (T4:T1) in the 85% of patients in whom the operating room staff were able to provide a TOF ratio. All patients had a 10-second pre-test with non-narcotic anesthesia (without muscle relaxant). The TOF ratio was determined after administration of a 0.01 mg/kg dose of cisatracurium besylate injection (0.4 mg/kg in patients aged 60 years or older). The TOF ratio was measured by the operating room staff at 10-second intervals until the TOF ratio reached 0.9 or the 120-second test was complete. The 120-second test was completed when the TOF ratio reached 0.9 or 120 seconds elapsed.

Table 1. Intubating Conditions at 120 Seconds* in Patients Undergoing Opioid/Nitrous Oxide/Oxygen Anesthesia in Study 4

<table>
<thead>
<tr>
<th>Patient Age</th>
<th>Successful Intubation</th>
<th>Intubation Difficulty</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-49 months</td>
<td>37/40 (93%)</td>
<td>3/40 (7.5%)</td>
</tr>
<tr>
<td>50-99 months</td>
<td>40/40 (100%)</td>
<td>0/40 (0%)</td>
</tr>
<tr>
<td>100-10 months</td>
<td>40/40 (100%)</td>
<td>0/40 (0%)</td>
</tr>
</tbody>
</table>

* Intubation difficulty was determined as follows: 1 = no difficulty; 2 = some difficulty; 3 = extreme difficulty; 4 = intubation impossible.

Table 13. Intubating Conditions at 120 Seconds* in Patients Undergoing Opioid/Nitrous Oxide/Oxygen Anesthesia in Study 4

<table>
<thead>
<tr>
<th>Patient Age</th>
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* Intubation difficulty was determined as follows: 1 = no difficulty; 2 = some difficulty; 3 = extreme difficulty; 4 = intubation impossible.

In Studies 2 and 3, cisatracurium besylate injection doses of 0.25 and 0.4 mg/kg were evaluated in 30 patients under opioid/nitrous oxide/oxygen anesthesia and provided 78 (66-86) and 91 (59-107) minutes of neuromuscular block for 60 minutes or longer. The average duration of continuous infusion was 62.8 minutes (range: 17 to 145 minutes). The overall mean infusion rate for 9 patients whose infusion was 45 minutes was 1.2 ± 0.2 mg/kg/h. The time to 90% neuromuscular blockade was 1 minute slower in patients with end-stage renal disease than in patients with normal renal function. Therefore, consider extending the interval between administering cisatracurium besylate injection.

Because the time to maximum neuromuscular blockade is approximately 1 minute slower in geriatric patients compared to younger patients, consider extending the interval between administering cisatracurium besylate injection.

The 20 mL single-dose vials contain 10 mg/mL cisatracurium, equivalent to 13.38 mg/mL cisatracurium besylate.

The 5 mL single-dose vials contain 2 mg/mL cisatracurium, equivalent to 2.68 mg/mL cisatracurium besylate.
Cisatracurium besylate injection is for intravenous use only.

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

FULL PRESCRIBING INFORMATION

Cisatracurium besylate injection is available as clear, colorless to slightly yellow or greenish yellow solution in the following strengths:

Store this diluted cisatracurium besylate injection solution under refrigeration for no more than 24 hours.

Cisatracurium besylate injection also may be diluted to 0.1 mg/mL or 0.2 mg/mL in the following solution:

Store these diluted cisatracurium besylate injection solutions either in a refrigerator or at room temperature for 24 hours without significant loss of potency.

The recommended cisatracurium infusion rate in adult patients in the ICU is 3 mcg/kg/minute (range: 0.5 to 10.2 mcg/kg/minute)

2.3 Recommended Maintenance Bolus Cisatracurium Besylate Injection Doses in Adult Surgical Procedures

neuromuscular blockade in an average of about 3 minutes (range: 1.5 to 8 minutes) with a clinically effective block for 36 minutes (range: 29 to 46 minutes)

The recommended dose of cisatracurium besylate injection for intubation of pediatric patients ages 1 month to 23 months is 0.15 mg/kg administered over 5 to 10 seconds. When administered during stable

50 to 60 minutes after an initial dose of cisatracurium besylate injection 0.2 mg/kg.

Use peripheral nerve stimulation and monitor the clinical signs of neuromuscular blockade to determine the adequacy of neuromuscular blockage and the need to adjust the

[see Drug Interactions (7.1) and

neuromuscular blocking agents, both depolarizing and non-depolarizing, has been reported.

extended administration of cisatracurium besylate injection may be at higher risk of seizures.

cisatracurium besylate injection-associated residual paralysis, extubation is recommended only after the patient has recovered sufficiently from neuromuscular blockade. Consider use of a reversal agent especially

8.10 Patients with Neuromuscular Disease

Because the time to maximum neuromuscular blockade is approximately 1 minute slower in geriatric patients compared to younger patients, consider extending the interval between administering cisatracurium

90 to 120 minutes to the administration of the second dose of 0.2 mg/kg to patients older than 65 years of age.