

Glycopyrrolate Injection, USP

0.6 mg per 3 mL



Now available in Simplist[®] ready-to-administer prefilled syringes exclusively from Fresenius Kabi

Glycopyrrolate Injection, USP 0.6 mg per 3 mL* Simplist prefilled syringes may be used with Neostigmine Methylsulfate Injection, USP 3 mg per 3 mL.

*Glycopyrrolate Injection, USP may be administered prior to or concomitantly with Neostigmine Methylsulfate Injection, USP for reversal of neuromuscular blockade. See package inserts for complete dosage and administration information at www.simplist-us.com.

Manufacturer prepared

24-month shelf life

Preservative free

Common concentration

Eliminates vial-to-syringe transfers

Glycopyrrolate Injection, USP

INDICATIONS AND USAGE

Glycopyrrolate Injection, for intramuscular or intravenous use, is an anticholinergic indicated:

in anesthesia (adult and pediatric patients)

- for reduction of airway or gastric secretions, and volume and acidity of gastric secretions, and blockade of cardiac inhibitory reflexes during induction of anesthesia and intubation.
- intraoperatively to counteract surgically or drug-induced or vagal reflex associated arrhythmias, and
- for protection against peripheral muscarinic effects of cholinergic agents.

in peptic ulcer (adults)

- as adjunctive therapy for the treatment of peptic ulcer when rapid anticholinergic effect is desired or oral medication is not tolerated.

IMPORTANT SAFETY INFORMATION

Do not use Glycopyrrolate Injection 0.6 mg per 3 mL single-dose prefilled syringe to administer a dose of less than 0.1 mg (0.5 mL).

Contraindications:

- Known hypersensitivity to glycopyrrolate or any of its inactive ingredients.
- Peptic ulcer patients with glaucoma; obstructive uropathy; obstructive disease of the gastrointestinal tract; paralytic ileus; intestinal atony of the elderly or debilitated patient; unstable cardiovascular status in acute hemorrhage; severe ulcerative colitis; toxic megacolon; complicating ulcerative colitis; myasthenia gravis.

Warnings and Precautions:

- **Precipitation of Acute Glaucoma:** Glycopyrrolate Injection may cause mydriasis and increase intraocular pressure in patients with glaucoma. Advise patients with glaucoma to promptly seek medical care if they experience symptoms of acute angle closure glaucoma.

• **Drowsiness or Blurred Vision:** May cause drowsiness or blurred vision. Advise patients not to drive or perform hazardous work until resolved.

• **Heat Prostration:** Advise patients to avoid exertion and high environmental temperatures after receiving Glycopyrrolate Injection.

• **Intestinal Obstruction:** Diarrhea may be an early symptom of incomplete intestinal obstruction. Avoid use in patients with diarrhea and ileostomy or colostomy.

• **Tachycardia:** Increase in heart rate may occur. Use with caution in patients with coronary artery disease, congestive heart failure, cardiac arrhythmias, hypertension, or hyperthyroidism.

Adverse Events: Most common adverse reactions are related to anticholinergic pharmacology and may include xerostomia (dry mouth); urinary hesitancy and retention; blurred vision and photophobia due to mydriasis (dilation of the pupil); cycloplegia; increased ocular tension; tachycardia; bradycardia; palpitation; and decreased sweating.

To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC at 1-800-551-7176, option 5, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Drug Interactions:

- Other anticholinergics or drugs with anticholinergic activity: May intensify the antimuscarinic effects and result in an increase in anticholinergic side effects.
- Potassium Chloride in a Wax Matrix: May increase severity of potassium chloride-induced gastrointestinal lesions.

Pediatric Use: Infants, patients with Down's Syndrome, and pediatric patients with spastic paralysis or brain damage may experience an increased response to anticholinergics, thus increasing the potential for side effects. Large doses may cause hyperexcitability.

This Important Safety Information does not include all the information needed to use Glycopyrrolate Injection, USP safely and effectively. Please see full prescribing information for Glycopyrrolate Injection, USP at www.fresenius-kabi.com/us.

Neostigmine Methylsulfate Injection, USP

INDICATIONS AND USAGE

Neostigmine Methylsulfate Injection, a cholinesterase inhibitor, is indicated for intravenous use for reversal of the effects of nondepolarizing neuromuscular blocking agents (NMBA) after surgery.

IMPORTANT SAFETY INFORMATION

An anticholinergic agent, e.g., atropine sulfate or glycopyrrolate, should be administered prior to or concomitantly with neostigmine methylsulfate.

Neostigmine is contraindicated in patients with:

- Hypersensitivity to neostigmine.
- Peritonitis or mechanical obstruction of the urinary or intestinal tracts.

Neostigmine has been associated with bradycardia: Atropine or glycopyrrolate should be administered prior to administration of neostigmine methylsulfate injection to lessen risk of bradycardia.

Coexisting Conditions: Patients with known cardiac disease, cardiac arrhythmias, or recent coronary artery occlusion may be particularly sensitive to the hemodynamic effects of neostigmine; their blood pressure and electrocardiogram should be continuously monitored with the initiation of neostigmine treatment and for a duration sufficient to assure hemodynamic stability.

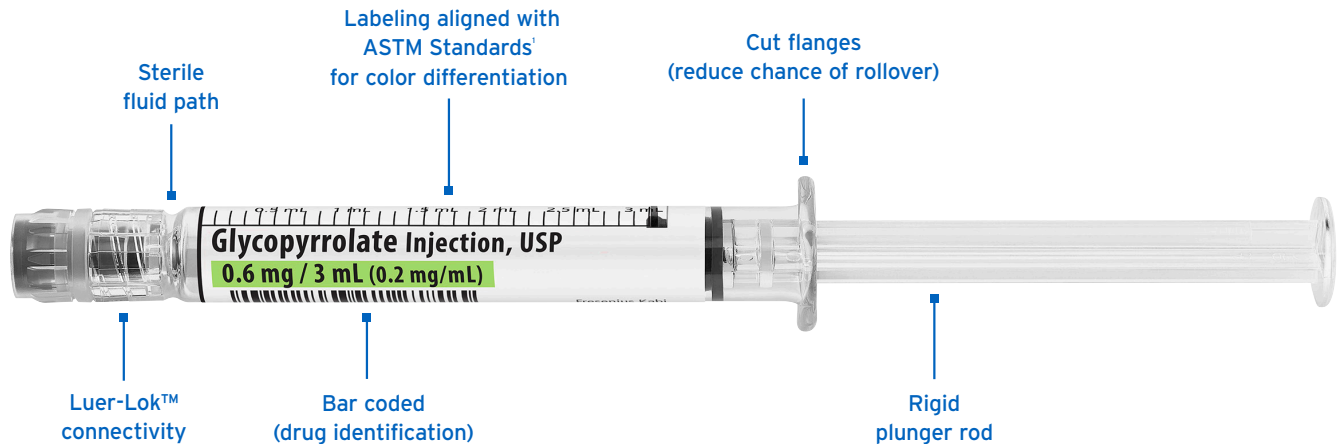
Neuromuscular Dysfunction: Can occur if large doses of neostigmine methylsulfate are administered when there is minimal neuromuscular blockade; reduce the dose if recovery from neuromuscular blockade is nearly complete.

Pregnancy: No human data and limited animal exist. Use only if clearly needed.

The most common adverse reactions include bradycardia, nausea, and vomiting.





To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC at 1-800-551-7176, option 5, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

This Important Safety Information does not include all the information needed to use Neostigmine Methylsulfate Injection safely and effectively. Please see full prescribing information for Neostigmine Methylsulfate Injection at www.fresenius-kabi.com/us.



No assembly required*

Ready-to-administer delivery systems can help improve patient safety and streamline drug preparation.^{2,3}

		
Product	Glycopyrrolate Injection, USP	Neostigmine Methylsulfate Injection, USP
Unit of Sale NDC Number (PK)	76045-023-30	76045-383-30
Description	Single Dose Simplist® Syringe	Single Dose Simplist® Syringe
Strengths	0.6 mg per 3 mL	3 mg per 3 mL
Concentrations	0.2 mg per 1 mL	1 mg per mL
Fill Volume	3 mL	3 mL
Unit of Sale	10	10
Bar Code	 (01)30376045023306	 N(01)30376045383301

**To place an order, contact your Sales Representative or call Customer Service at
1.888.386.1300 | www.simplist-us.com**

*Medications that are administered intramuscularly require a needle be attached to the syringe.

1. ASTM Designation: D4774 - 11, "Standard Specification for User Applied Drug Labels in Anesthesiology" <https://www.astm.org/Standards/D4774.htm>
 2. Institute for Safe Medication Practices. ISMP safe practice guidelines for adult IV push medications: a compilation of safe practices from the ISMP Adult IV Push Medication Safety Summit. <http://www.ismp.org/Tools/guidelines/ivsummitpush/ivpushmedguidelines.pdf>. Accessed July 11, 2017. 3. Fanikos J, Burger M, Canada T. An assessment of currently available i.v. push medication delivery systems. Am J Health Syst Pharm. 2017;74(9):e230-e235.