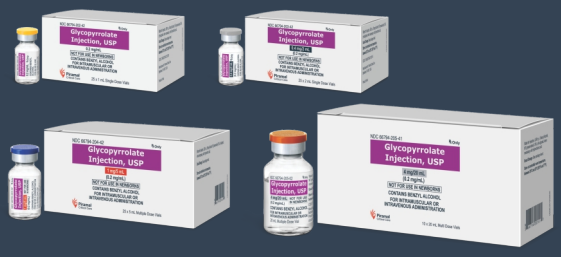
Anticholinergic

Piramal Critical Care



Glycopyrrolate Injection, USP

Piramal's Glycopyrrolate Injection, USP is available through the wholesaler or distributor of your choice

Wholesaler / Distributor Name	25 x 1 mL Single Dose Vials in a carton: NDC - 66794-202-42 Glycopyrrolate Injection, USP (0.2mg/mL) Catalog numbers	25 x 2 mL Single Dose Vials in a carton: NDC - 66794-203-42 Glycopyrrolate Injection, USP (0.4mg/2mL) Catalog numbers	25 x 5 mL Multiple Dose Vials in a carton: NDC - 66794-204-42 Glycopyrrolate Injection, USP (1mg/5mL) Catalog numbers	10 x 20 mL Multi Dose Vials in a carton: NDC - 66794-205-41 Glycopyrrolate Injection, USP (4mg/20mL) Catalog numbers
AmerisourceBergen	10221438	10221437	10221524	10221525
Cardinal	5536982	5536990	5537006	5537014
McKesson	3949518	3949534	3949559	3949567
Morris & Dickson	630244	630251	630269	630277

ABBREVIATED PRESCRIBING INFORMATION

PRODUCT NAME AND COMPOSITION: Glycopyrrolate, a synthetic anticholinergic agent for Intramuscular (IM) or Intravenous (IV) administration. Supplied in 1, 2, 5 and 20 mL vials, all containing Glycopyrrolate 0.2 mg/mL.

Please refer to Full Prescribing Information (FPI) before prescribing.

INDICATIONS: In Anesthesia, as a preoperative antimuscarinic to reduce salivary, tracheobronchial, and pharyngeal secretions; to reduce the volume and free acidity of gastric secretions; and to block cardiac vagal inhibitory reflexes during induction of anesthesia and intubation. In **Peptic Ulcer**, as adjunctive therapy for the treatment of peptic ulcer when rapid anticholinergic effect is desired or when oral medication is not tolerated.

DOSAGE AND ADMINISTRATION: See FPI for full details. As **preanesthetic medication**, the recommended dose is 0.004 mg/kg by intramuscular injection, given 30 to 60 minutes prior to the anticipated time of induction of anesthesia or at the time the preanesthetic narcotic and/or sedative are administered. As **intraoperative medication**, Glycopyrrolate injection may be used during surgery to counteract drug-induced or vagal reflexes and their associated arrhythmias (e.g., bradycardia). It should be administered intravenously as single doses of 0.1 mg and repeated, as needed, at intervals of 2 to 3 minutes. For the **reversal of neuromuscular blockade**, the recommended dose of Glycopyrrolate injection is 0.2 mg for each 1.0 mg of neostigmine or 5.0 mg of pyridostigmine. In **peptic ulcer** the usual recommended dose of Glycopyrrolate injection is 0.1 mg administered at 4-hour intervals, 3 or 4 times daily intravenously or intramuscularly. **Pediatric Patients**: As preanesthetic medication, the recommended dose is the same as that recommended for adults; in infants (1 month to 2 years of age), the dose can be increased to 0.009 mg/kg.

CONTRAINDICATIONS: Known hypersensitivity to Glycopyrrolate or any of its inactive ingredients. In the management of peptic **ulcer patients**, because of the longer duration of therapy, Glycopyrrolate injection may be contraindicated in patients with glaucoma, obstructive uropathy, and myasthenia gravis. See FPI for full details.

COMMON SIDE EFFECTS: Glycopyrrolate, like all can produce certain effects, most of which are extensions of their pharmacologic actions. Adverse reactions 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; palpitation; decreased sweating; loss of taste; headache; nervousness; drowsiness; weakness; dizziness; insomnia; nausea; vomiting; impotence; suppression of lactation; constipation; bloated feeling; severe allergic reactions including anaphylactic/anaphylactoid reactions; hypersensitivity; urticaria, pruritus, dry skin, and other dermal manifestations; some degree of mental confusion and/or excitement, especially in elderly persons. See FPI for a complete list.

WARNINGS AND PRECAUTIONS: Glycopyrrolate should be used with great caution in patients with glaucoma. Due to its benzyl alcohol content, Glycopyrrolate injection should not be used in neonates. See FPI for full details.

OVERDOSAGE: To combat serious peripheral anticholinergic effects due to overdosage, a quaternary ammonium anticholinesterase such as neostigmine methylsulfate may be given intravenously in increments of 0.25 mg in adults. This dosage may be repeated every five to ten minutes until anticholinergic overactivity is reversed or up to a maximum of 2.5 mg. If CNS symptoms (e.g., excitement, restlessness, convulsions, psychotic behavior) occur, physostigmine (which does cross the blood-brain barrier) may be used. Physostigmine 0.5 to 2 mg should be slowly administered intravenously and repeated as necessary up to a total of 5 mg in adults. Following overdosage, a curare-like action may occur, i.e., neuromuscular blockade leading to muscular weakness and possible paralysis. In the event of a curare-like effect on respiratory muscles, artificial respiration should be instituted and maintained until effective respiratory action returns.

For more information, please contact Piramal Customer Service at +1-800-414-1901 during business hours (8 a.m. EST to 5 p.m. EST) or e-mail at pcc.customerservice@piramal.com

- Full prescribing information of Glycopyrrolate Injection, USP can be seen at https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=83d70378-011b-4ce3-e053-2991aa0a22be.
- Adverse events should be reported to Piramal Critical Care at http://pcc-chex.force.com/SiteComplaintForm.
- You are encouraged to report adverse events of prescription drugs to the FDA. Visit MedWatch or call 1-800-FDA-1088.

"Saving and Improving Patients' Lives."

Piramal Critical Care

Piramal Critical Care, Inc.
3950 Schelden Circle, Bethlehem, PA 18017, USA
Toll Free No.: +1-800-414-1901 www.piramalcriticalcare.com/us/

https://www.linkedin.com/company/piramal-critical-care/

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