



## Meitheal – Recall of glycopyrrolate injection

- On September 3, 2021, **Meitheal announced** a voluntary, user level recall of four lots of **glycopyrrolate injection** because of an out of specification result observed for benzaldehyde content during routine quality testing of stability samples at the 18-month timepoint.
- This product was manufactured by Caplin Steriles Limited and distributed by Meitheal Pharmaceuticals from June 19, 2020 through May 24, 2021:

| Product Description                        | NDC #                        | Lot# (Expiration Date)   |
|--|------------------------------|--|
| Glycopyrrolate injection<br>4 mg per 20 mL | 71288-408-21<br>71288-408-20 | G0010120 (12/2021);<br>G0080520 (4/2022);<br>G0090221 (1/2023);<br>G0100221 (1/2023) |

- Glycopyrrolate injection is indicated for use 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; and for use in adults as adjunctive therapy for the treatment of peptic ulcer when rapid anticholinergic effect is desired or when oral medication is not tolerated.
- Benzaldehyde is an aromatic compound and can impact several organs like the brain, liver and kidney. Higher percentages of benzaldehyde concentration observed (up to 1%) is expected to result into negligible health risk. Although the occurrence of serious adverse events could not be ruled out.
- To date, Meitheal has not received reports of any adverse events or identifiable safety concerns attributed to the recalled lots.
- Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to the recalled glycopyrrolate injection.
- Anyone with an existing inventory of the recalled product should stop use, distribution and quarantine the product immediately.
- Contact Meitheal at **1-844-824-8426** for further information regarding this recall.



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