

Product Recall: Meitheal Pharmaceuticals - Carton labeled properly as cisatracurium, but the vials within are mislabeled as phenylephrine but actually contain cisatracurium.- URGENT – HAZARDOUS SITUATION

The Board of Pharmacy has received notice of the following product recall:

Product Name: Carton labeled properly as cisatracurium, but the vials within are mislabeled as phenylephrine but actually contain cisatracurium.

NDC: 71288-712-06

Package Size: 10 mg per 5mL (2 mg per mL)

ISMP is aware of an extremely hazardous packaging error involving certain cisatracurium products from Meitheal Pharmaceuticals. While the outer carton identifies the vials inside as cisatracurium, the vials contained in the carton are labeled phenylephrine injection. The vials actually contain cisatracurium and have caps appropriate for a paralyzing agent. However, this cap warning may not be noticed, since the vial is labeled phenylephrine.

Due to the nature of this situation and the potential for death if these vials are used as phenylephrine injection in patients who are not intubated and ventilated, we urge facilities to immediately examine any and all cartons of cisatracurium from Meitheal Pharmaceuticals for this serious packaging error. The possibility that any of these vials were actually distributed should also be considered. ISMP has confirmed that both the FDA and the manufacturer are aware of this situation and that a recall is imminent.

The Board of Pharmacy strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.