Meitheal Pharmaceuticals – Recall of cisatracurium injection

- On January 27, 2021, Meitheal announced a voluntary, user level recall of one lot of cisatracurium injection because a product complaint revealed that a portion of one lot of cartons labeled as cisatracurium injection 10 mg/5 mL, containing ten vials per carton, contained ten vials mis-labeled as phenylephrine hydrochloride injection 100 mg/10 mL.

- Meitheal commenced shipping the product on August 19, 2020 which was distributed to wholesalers nationwide in the U.S.:

Product Description	NDC#	Lot# (Expiration Date)
Cisatracurium besylate injection, 10 mg per 5 mL	71288-712-06 (unit of sale); 71288-712-05 (unit of use)	C11507A* (10/2021)

*Note: Mis-labeled product will have this same lot number of C11507A and expiration date of 10/2021 but will be labeled on the vial as phenylephrine hydrochloride injection.

- Cisatracurium injection is indicated as an adjunct to general anesthesia to facilitate tracheal intubation in adults and in pediatric patients 1 month to 12 years of age; to provide skeletal muscle relaxation in adults during surgical procedures or during mechanical ventilation in the intensive care unit; and to provide skeletal muscle relaxation during surgical procedures via infusion in pediatric patients 2 years and older.

- There is a reasonable probability that a patient who requires cisatracurium for muscle paralysis as part of general anesthesia is administered phenylephrine instead would not receive any skeletal muscle relaxation and could cause a hyperadrenergic state resulting in elevated blood pressure, arrhythmia and cardiac/brain ischemia. If this is not quickly diagnosed and treated, severe illness or death can occur.

- There is a reasonable probability that a patient who requires phenylephrine to increase their blood pressure, such as patients with severely low blood pressure, especially resulting from septic shock who is administered cisatracurium instead could result in a fast onset of muscle paralysis and decrease in oxygen. If this is not quickly diagnosed and treated, severe illness or death can occur within minutes.

- To date, Meitheal has not received reports of any adverse events or identifiable safety concerns attributed to the recalled lot.

- Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to the recalled cisatracurium 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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