AuroMedics – Recall of polymyxin B for injection

- On January 28, 2022, the FDA announced a recall of one lot of AuroMedics' polymyxin B for injection to the consumer level due to a product complaint for the presence of particulate matter, identified as hair being discovered in a vial.
- The recalled batch was distributed from March 19, 2021 through June 14, 2021.

Product Description	NDC	Lot # (Expiration Date)
Polymyxin B for injection, 500,000 units/vial	55150-234-10	CPB200013 (9/2022)

- Polymyxin B for injection is a sterile, white lyophilized cake or powder, suitable for preparation of sterile solutions for intramuscular, intravenous, intrathecal, or ophthalmic use indicated in the treatment of infections or the urinary tract, meninges (membranes that protect the brain and spinal cord), and bloodstream caused by susceptible strains of bacteria.
- The administration of an intravenous product containing hair, even with the use of a filter, could cause a patient to experience serious hypersensitivity reactions that may be life-threatening.
- To date, AuroMedics has not received reports of any adverse events or identifiable safety concerns attributed to the product consumed from this lot.
- Patients who have the recalled polymyxin B for injection should stop using the product and return to place of purchase and contact their physician as appropriate.
- Anyone with an existing inventory of the recalled product should stop distribution and quarantine the product immediately.
- Contact AuroMedics by phone at **1-866-850-2876** (option 2) or by email at **pvg@aurobindousa.com** for more information about the recall.