Polymyxin B for Injection Recall Alert

Date of Notice: January 28, 2022

Brief Description of Recall Alert

AuroMedics Pharma LLC has initiated a voluntary recall of lot number CPB200013 of polymyxin B for injection USP, 500,000 units/vial, due to a product complaint for the presence of particulate matter, identified as hair being discovered in a vial within this lot. AuroMedics Pharma, LLC shipped the entire lot to wholesalers nationwide from March 19, 2021, through June 14, 2021.

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.

Affected Products

Drug Name & Strength	NDC	Lot	Expiration Date
polymyxin B for injection USP, 500,000 units/vial	55150-234-10	CPB200013	09/2022

Prescriber Information

AuroMedics Pharma, LLC is notifying its distributors by recall letters and is arranging for return/ replacement of all recalled product. Consumers/distributors/retailers that have the product lot which is being recalled should immediately stop using and return to place of purchase. To date, AuroMedics Pharma, LLC has not received reports of any adverse events or identifiable safety concerns attributed to the product consumed from this lot.

If you have any general questions regarding the return of this product, please contact Qualanex at 1-888-280-2046 or email recall@qualanex.com (live calls received 8:00 am to 5:00 pm Monday - Friday EST).

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online.
- Regular Mail or Fax: Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Member Information

Members should contact their doctor or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Members with medical-related questions, who wish to report an adverse event or quality issues about the product being recalled, should contact AuroMedics Pharma, LLC from 8:00 am to 5:00 pm Monday - Friday EST, by phone at 866-850-2876 (option 2) or by email at pvg@aurobindousa.com.

RxAdvance Response

Members should contact their doctor or pharmacist immediately to provide replacement drug (if needed) or a different treatment option. RxAdvance is in the process of contacting members and prescribers to advise them of this recall.