FDA MedWatch

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Piperacillin and Tazobactam for Injection, USP 3.375 g Vials by AuroMedics Pharma: Recall - Vials Contain Particulate Matter

ISSUE: AuroMedics Pharma is voluntarily recalling two lots of Piperacillin and Tazobactam for Injection, USP 3.375 g (Piperacillin Sodium equivalent to 3 g of Piperacillin USP and Tazobactam Sodium equivalent to 0.375 g of Tazobactam USP. Each vial contains 7.05 mEq (162 mg) of Sodium) in a Single-Dose vial, to the hospital level.

The products have been found to contain particulate matter, visible only after reconstitution that was confirmed to be glass within the vial. The administration of a glass particulate, if present in an intravenous drug, may result in local irritation or swelling in response to the foreign material. More serious potential outcomes would include blockage and clotting in blood vessels, which may be life-threatening.

To date, AuroMedics Pharma has not received reports of any adverse events or identifiable safety concerns attributed to the product consumed from these lots.

BACKGROUND: Piperacillin and Tazobactam for Injection is used for treatment of patients with moderate to severe infections caused by susceptible isolates of the designated bacteria in intra-abdominal, skin and skin structure and female pelvic infections as well as community acquired and nosocomial pneumonia.

It is packaged in a carton containing 10 single-dose vials, NDC: 55150-120-30. **The affected Piperacillin and Tazobactam for Injection lots being recalled are PP0317061-A, Exp. Aug 2019, and PP0317049-A, Exp. Aug 2019.**

RECOMMENDATION: AuroMedics Pharma is notifying its distributors and customers by recall letters and is arranging for return/replacement etc. of all recalled product. Consumers/distributors/retailers that have the product lots which are being recalled should immediately stop using and return to place of purchase/contact their doctor as appropriate.

Consumers with questions regarding this recall can contact AuroMedics Customer Service on weekdays from 9:00AM to 5:00PM EST at 888-238-7880 Option 1. If you need assistance in returning your product or have questions about the recall process, contact Inmar at 800-967-5952 weekdays Monday through Friday 8:30 AM to 5:00 PM EST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- 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