



FDA MedWatch

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AuroMedics Pharma LLC Issues Voluntary Nationwide Recall of Piperacillin and Tazobactam for Injection 3.375 grams per vial, Due to Presence of Particulates Identified as Glass and Silicone Material

Announcement: AuroMedics Pharma LLC 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. One vial from lot# PP0317012-A was found to contain particulate matter, identified as glass within the vial and another vial from lot# PP0317059-A was found to contain silicone material. This problem was discovered as a result of two product complaints in which the contents of one vial from batch PP0317012-A was found to contain a glass particle and the contents of one vial from batch PP0317059A was found to contain a silicone particle.

Risk Statement: The administration of glass or silicone particulates 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 LLC has not received reports of any adverse events or identifiable safety concerns attributed to the product consumed from these lots.

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 PP0317059-A; Exp. February 2019: PP0317012-A, Exp. August 2019. The product can be identified as a 'clear vial stoppered with grey rubber stopper and sealed with aluminum seals having a Royal Blue color polypropylene disc'. AuroMedics shipped the entire lot PP0317012-A to wholesalers and/or hospitals nationwide June 30, 2017. Lot PP0317059-A was shipped 27 November 2017 through 29 January 2018.

The product label is as shown below:

AuroMedics Pharma LLC 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.

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

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm 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.

	Each vial contains: Piperacillin sodium and tazobactam sodium equivalent to piperacillin USP 3 g and tazobactam USP 0.375 g and 7.05 mEq (162 mg) of sodium.	NDC 55150-120-30	Manufactured for: AuroMedics Pharma LLC 6 Wheeling Road Dayton, NJ 08810	
	Usual Dosage: See package circular for reconstitution instructions and complete directions for use.		Made in India	M.L.No.: 07/MN/TS/2016/9/0
	Contains no preservative.	3.375 grams per vial		P1416118
	STORAGE <i>Prior to Reconstitution:</i> Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. <i>After Reconstitution:</i> See package insert.	For Intravenous Use Only	Batch :	Expiry:
		Single-Dose Vial		
	Rx only			
	AUROMEDICS		e1	