FDA MedWatch

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Ampicillin and Sulbactam for Injection USP, 3 g Single-Dose Vials by AuroMedics Pharma: Recall - Presence of Red Particulate Matter

ISSUE: AuroMedics Pharma is voluntarily recalling two lots of Ampicillin and Sulbactam for Injection USP, 3 g/Single-Dose vials, to the hospital/user level. The recall has been initiated due to customer complaints of the presence of red particulate matter in the product that is believed to be red rubber particles from the manufacturing process of the active ingredients.

In the event the particulate is administered to the patient, it may result in local site reaction, phlebitis, pulmonary granuloma, occlusion of blood vessels, thromboembolic events and systemic immune response. Patients with vascular disease may be at particular risk of embolic events which could cause permanent impairment or damage to a body structure or function. The risk is reduced by the possibility of detection.

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: Ampicillin and Sulbactam for Injection is an intravenously or intramuscularly administered antibiotic used for the treatment of infections due to susceptible strains in adults and pediatric patients one year and older. It is packaged in a carton containing 10 vials, NDC 55150-117-20. **The affected Ampicillin and Sulbactam for Injection lots being recalled are AS0317041-A, Exp. Aug 2019, and AS0317035-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 lot which is 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 Monday through Friday 9:00 AM to 5:00 PM 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 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 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: www.fda.gov/MedWatch/report
- 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