AuroMedics – Recall of ampicillin/sulbactam and piperacillin/tazobactam injection products

- On May 8, 2018, the FDA announced recalls of AuroMedics' ampicillin/sulbactam and piperacillin/tazobactam injection products.

- Ampicillin/sulbactam is being recalled 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.

- Piperacillin/tazobactam is being recalled due to particulate matter, visible only after reconstitution, which was confirmed to be glass within the vial.

- The recalled lots of ampicillin/sulbactam were shipped from October 19, 2017 through October 26, 2017. The recalled lots of piperacillin/tazobactam were shipped from December 6, 2017 through April 25, 2018.

Product Description	NDC #	Lot # (expiration date)
Ampicillin/sulbactam for injection, 3 grams per single dose vial	55150-117-20	AS0317041-A (8/2019); AS0317035-A (8/2019)
Piperacillin/tazobactam for injection, 3.375 grams per single-dose vial	55150-120-30	PP0317061-A (8/2019); PP0317049-A (8/2019)

- Ampicillin/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 ≥ 1 year of age.

- Piperacillin/tazobactam for injection is used for the 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.

- Infused particulate matter may result in local site reactions, 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 recalled products.

- Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using a recalled product.

  Anyone with recalled product should immediately stop use, return the product to the place of purchase, and contact their physician or healthcare provider as appropriate.

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- For more information regarding these recalls, contact AuroMedics Customer Service at **1-888-238-7880.**