Alerts and Recalls

Generic Name (Trade Nameâ€"Company)

May 14, 2018

Piperacillin and tazobactam for injection, 3.375 g vials

(No trade name—AuroMedics Pharma)

Recalled product contains glass particulate matter

Uses/Notes

AuroMedics Pharma is voluntarily recalling two lots (PP0317061-A, exp. Aug 2019, and PP0317049-A, exp. Aug 2019) of piperacillin and tazobactam for injection, 3.375 g (piperacillin sodium equivalent to 3 g of piperacillin and tazobactam sodium equivalent to 0.375 g of tazobactam) to the hospital level. Each single-dose vial contains 7.05 mEq (162 mg) of sodium.

The medication is packaged in a carton containing 10 single-dose vials (NDC: 55150-120-30).

The products have been found to contain particulate matter, visible only after reconstitution, that was confirmed to be glass within the vial.

Administration of a glass particulate, if present in I.V. 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.

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.

AuroMedics Pharma is notifying its distributors and customers by recall letters and is arranging for return and replacement of all recalled product.

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

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