Company Announcement

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

AuroMedics Pharma LLC Issues Voluntary Nationwide Recall of Pantoprazole Sodium for Injection 40 Mg Per Vial, Due to Presence of Glass Particles in the Vial.

For Immediate Release

December 19, 2017

Contact

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Announcement

View Product Photos

East Windsor, New Jersey, AuroMedics Pharma LLC is voluntarily recalling one lot of Pantoprazole Sodium for Injection 40 mg per vial, to the hospital level. The product was found to contain glass particles in the vial. This problem was discovered as a result of a product complaint in which the contents of one vial from one batch was found to contain a piece of glass.

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 LLC has not received reports of any adverse events or identifiable safety concerns attributed to this recall.

Pantoprazole Sodium for Injection 40 mg per vial, is used for short term treatment of gastroesophageal reflux disease associated with a history of erosive esophagitis and pathological hypersecretion including zollinger-ellison syndrome and is packaged in a carton containing 10 vials, NDC: 55150-202-10. The affected Pantoprazole Sodium for Injection lot being recalled is CPO170035, EXP. May

2019. The product can be identified as ‘vial stoppered with grey slotted rubber stopper and sealed with aluminum seals having Sky Blue color polypropylene disc’. AuroMedics commenced shipping the product to customers on August 7, 2017 and was distributed to wholesalers and/or hospitals nationwide.

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 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 Aurobindo Customer Service weekdays 9:00AM to 5:00PM EST at 866-850-2876 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 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.htm (http://www.fda.gov/MedWatch/report.htm)**
- **Regular Mail or Fax**: Download form **www.fda.gov/MedWatch/getforms.htm (http://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

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

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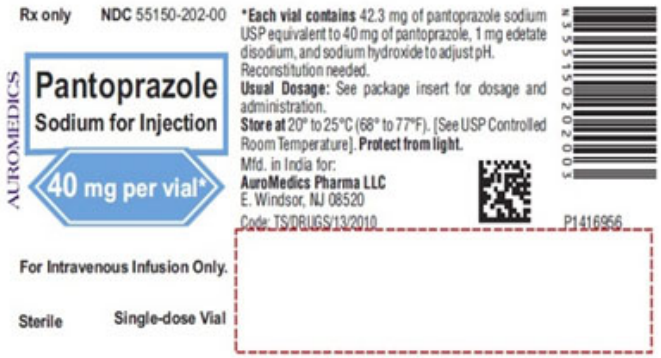
Product Photos



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