U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

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.

Sagent Pharmaceuticals Initiates a Nationwide Voluntary Recall of Oxacillin for Injection, USP, 10g Due to Presence of Iron Oxide Particulate Matter

For Immediate Release

August 18, 2016

Contact

Consumers

Customer Call Center
(866) 625-1618

Announcement

Sagent Pharmaceuticals, Inc. today announced the voluntary nationwide recall of one lot of Oxacillin for Injection, USP, 10 g (NDC 25021-163-99) Lot OXT512 (Exp. Date March 2017) manufactured by Astral SteriTech Private Limited and distributed by Sagent. Sagent has initiated this voluntary recall to the user level due to the receipt of a product complaint for a single vial containing small, dark particulate matter found within the solution after reconstitution. The particulate matter has been identified as iron oxide.

In the event that metal particulate in an injectable product is administered to a patient, it may result in local swelling, irritation of blood vessels or tissue, or blockage of blood vessels. Blockage of blood vessels can lead to serious events, which may be life-threatening, such as stroke, heart attack, respiratory failure, kidney failure, or liver failure.

To date, Sagent is not aware of any known adverse patient events resulting from the use of the subject product lot.

The product is packaged in cartons containing 10 x 10 gram Pharmacy Bulk Package bottles identified by NDC 25021-163-99. The lot number being recalled is Lot OXT512 which was distributed to hospitals, wholesalers and distributors nationwide from June 2016 through July 2016. Oxacillin for Injection, USP, 10 g is indicated in the treatment of infections caused by penicillinase producing staphylococci which have demonstrated susceptibility to the drug. It is available by prescription only.

Customers are being notified by fax, email, FedEx, and/or certified mail that includes arrangements for the return of all recalled product. Customers have been instructed to examine their inventory immediately and to quarantine, discontinue distribution of and return the recalled lot of product. Customers who may have further distributed this product have been requested to identify their customers and notify them at once of this product recall. The necessary form by which to document this information as well as other information regarding this recall is available at **www.Sagentpharma.com (http://www.sagentpharma.com/)**.

Any questions about returning unused product should be directed to the Customer Call Center at (866) 625-1618 M-F 8am-7pm CST. Healthcare workers who have medical questions about Oxacillin for Injection, USP may contact Sagent Medical Affairs (866-625-1618, Option 3) M-F 8am-5pm CST.

Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this 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

About Sagent Pharmaceuticals, Inc.
Sagent Pharmaceuticals, Inc., founded in 2006, is a leading provider of affordable pharmaceuticals to the hospital market. Sagent has created a unique, global network of resources, comprising rapid development capabilities, sophisticated manufacturing and innovative drug delivery technologies, resulting in an extensive and rapidly expanding pharmaceutical product portfolio that fulfills the evolving needs of patients.

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