Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: August 8, 2014

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: Laurie Kidwell, RRT/Supervisor
Food Protection Program

SUBJECT: Cubist Pharmaceuticals, Inc. – RECALL [Drug]

AFFECTED PRODUCT: **CUBICIN® (daptomycin for injection)**

SUMMARY: **Unclassified Recall; The recall is due to the potential presence of glass particulate matter in vials.**

CUBICIN (Daptomycin For Injection) 500 mg in 10 mL in a single-use vial packaged in a carton (refer to www.cubicin.com).

CUBICIN was distributed nationwide to multiple consignees.

SUGGESTED ACTION: **For consumer inquiry only. For healthcare professionals and pharmacists with medical questions regarding this recall may contact Cubist Medical Information at (877) 282-4786 between the hours of 8 a.m. to 5:30 p.m. EDT, Monday through Friday.**

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Cubist Pharmaceuticals Issues Voluntary U.S. Recall Of Certain Lots Of CUBICIN (Daptomycin For Injection) 500 mg In 10 mL Single Use Vials Due To Presence Of Particulate Matter

Contact:
Consumer:
877-282-4786

FOR IMMEDIATE RELEASE - August 6, 2014 - Cubist Pharmaceuticals, Inc. (NASDAQ: CBST) today announced it is voluntarily recalling certain lots of CUBICIN® (daptomycin for injection) to the user level due to the potential presence of glass particulate matter in vials produced by a contract manufacturer. Please click here for the list of affected CUBICIN lot information.

The administration of a glass particulate, if present in an intravenous drug, poses a potential safety risk to patients such as a thromboembolism or a life-threatening pulmonary emboli. Other events such as phlebitis, mechanical block of the capillaries or arterioles, activation of platelets, or subsequent generation of microthrombi are also possible. Patients with a preexisting condition of trauma or other medical condition that adversely affects the microvascular blood supply are at an increased risk. Administration of a glass particulate can also lead to formation of granulomas, which represent a protective local inflammatory response to the foreign material.

Cubist has decided to issue a voluntary recall of these lots as a result of an issue with a manufacturing line of one of our suppliers that could result in glass particulate matter in vials. No complaints of glass in vial or adverse events in association with a product complaint of glass in vial have been reported to date for these recalled lots.

CUBICIN is an intravenously administered prescription product indicated for the treatment of skin infections and certain blood stream infections. CUBICIN is supplied in a single-use vial packaged in a carton (refer to www.cubicin.com). CUBICIN was distributed nationwide to multiple consignees.

Cubist is notifying customers by letter and phone. Anyone with an existing inventory of the product lots listed should determine whether they have product from the recalled lots, quarantine, and discontinue distribution of this recalled lots of the product and call Cubist at (855) 534-8309 between the hours of 9 a.m. to 7 p.m. EDT, Monday through Friday, to arrange for return and replacement of the affected lots.

As noted in the package insert for CUBICIN, parenteral drug products should be carefully inspected visually for particulate matter prior to administration. Healthcare providers should not use any CUBICIN vials containing particulate matter.

Patient safety is Cubist's top priority and the Company wants to ensure that patients and the healthcare professionals using CUBICIN are aware of this recall and of what actions, if any, they should take. Cubist is arranging for return of recalled product. An internal investigation has identified the root cause as a manufacturing issue with a single manufacturing line of one of our suppliers, and Cubist has suspended all manufacturing on this line.

For healthcare professionals and pharmacists with medical questions regarding this recall may contact Cubist Medical Information at (877) 282-4786 between the hours of 8 a.m. to 5:30 p.m. EDT, Monday through Friday.

To report an adverse event or a product complaint, please call (877) 282-4786. Adverse events or quality problems experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Events Program either online, by regular mail or by fax.

- **Complete and submit the report Online**: http://www.fda.gov/MedWatch/report.htm

- **Regular mail or Fax: Download form** 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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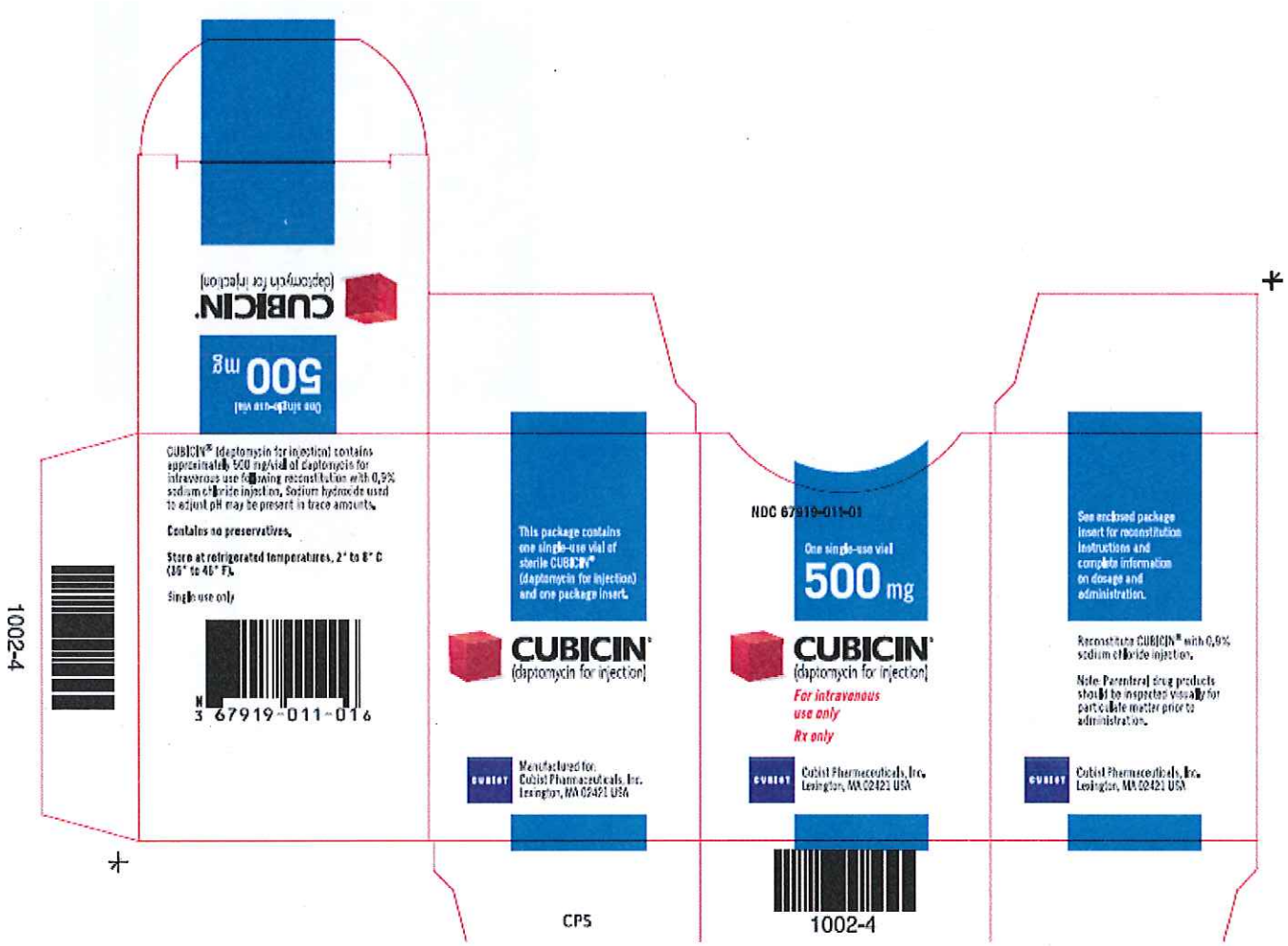
Photos



NDC 67919-011-01

Store at 2° to 8° C
(36° to 46° F).

CUBIST

Manufactured for:
Cubist Pharmaceuticals, Inc.
Lexington, MA 02421 USA

500 mg

CUBICIN®
(daptomycin for injection)

For intravenous use only
Single use only
Rx only

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67919-011-01