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.

Alvogen Issues Voluntary Nationwide Recall of Clindamycin Injection Due to a Potential for a Lack of Sterility Assurance

For Immediate Release

June 16, 2017

Contact

Consumers

(844) 842-8672

Medical Related Questions

(866) 770-3024

Announcement

Alvogen is voluntarily recalling seven lots of Clindamycin Injection USP ADD-Vantage Vials to the hospital/retail level due to microbial growth detected during a routine simulation of the manufacturing process, which represents the potential introduction of microorganisms into the product. Clindamycin Injection is manufactured for Alvogen by Hospira Inc., a Pfizer Company.

In the event that impacted product is administered, there is a reasonable probability that the patient may experience adverse events, ranging from fever, chills and malaise, to severe adverse events including systemic invasive mycoses or systemic bacterial sepsis. The possibility of a breach in sterility assurance in distributed product, while remote, cannot be eliminated. To date, Alvogen has not received any reports of adverse events associated with use of the product.

Clindamycin Injection, USP is indicated in the treatment of serious infections caused by susceptible bacteria. Its use should be reserved for penicillin-allergic patients or other patients for whom, in the judgment of the physician, a penicillin is inappropriate. The recalled list of products below were distributed Nationwide in the USA to wholesalers and hospitals between May 2016 and June 2017.

The recalled lots are:

Lot number	Expiration Date	Strength	NDC #
68-104-EV	07/31/2018	600mg/4mL	47781-463-69
68-105-EV	07/31/2018	900mg/6mL	47781-464-69
68-106-EV	07/31/2018	900mg/6mL	47781-464-69
73-154-EV	12/31/2018	300mg/2mL	47781-462-69
73-155-EV	12/31/2018	600mg/4mL	47781-463-69
73-156-EV	12/31/2018	600mg/4mL	47781-463-69
73-157-EV	12/31/2018	900mg/6mL	47781-464-69

Alvogen is notifying its distributors and customers via an Urgent Drug Recall Notice and is arranging for return of all recalled products. Anyone with existing inventory is requested to stop use and further distribution of the impacted lots, and quarantine the product immediately.

If you have Customer Service related questions, please contact Alvogen, Inc. at: (844) 842-8672, between the hours of 7:30am – 5:00pm ET, Monday though Friday. For Medical related questions, please contact Alvogen, Inc. at: (866) 770-3024, between the hours of 8:00am – 4:30pm ET, Monday through Friday. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to 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/Safety/MedWatch/HowToReport/DownloadForms/default.htm (https://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.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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