

# **Daptomycin for Injection Recall Alert**

Date of Notice: 07/07/2020

### **Brief Description of Recall Alert**

Mylan N.V. today announced that its U.S.-based Mylan Institutional LLC business is conducting a voluntary nationwide recall of one lot of daptomycin for injection, 500 mg/vial due to the presence of particulate matter found in one single-dose vial manufactured by Mylan Laboratories Limited's Specialty Formulation Facility. This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Intravenous administration of a solution containing visible particulates could lead to serious adverse events including, but not limited to, local irritation, vasculitis/phlebitis, antigenic or allergic reactions, and microvascular obstruction, including pulmonary embolism.

## **Affected Products**

Drug Name & Strength	NDC	Lot	Expiration Date
daptomycin for injection 500 mg/20 mL vial	67457-813-50	7605112	10/2021

#### **Prescriber Information**

Adverse reactions or quality problems experienced with the use of this drug 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 <u>Online</u>
- Regular Mail or Fax: <u>Download form</u> 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

#### **Member Information**

Members that are in possession of recalled product should contact Stericycle at 1-888-641-9736 for the return of the recalled product. Normal business hours are Monday through Friday 8 a.m. to 5 p.m. EST.

Members with questions regarding this recall can contact Mylan Customer Relations at 1-800-796-9526 or customer.service@mylan.com, Monday through Friday from 8 a.m. – 5 p.m. EST. Members should contact their doctor if they have experienced any problems that may be related to using these drug products.

#### **RxAdvance Response**

RxAdvance recommends that you speak to your doctor before you stop taking the drug. RxAdvance is in the process of contacting members and prescribers to advise them of this recall.

This document is designed to be an informational resource to facilitate discussion and should be used neither as a basis for clinical decision-making or treatment nor as a substitute for reading original literature. RxAdvance makes every effort to ensure that the information provided is up-to-date, accurate, and complete, but no guarantee is made to that effect. If this information is provided to clients or vendors, it is subject to any contractual confidentiality provisions. Third-party disclosures are in violation of confidentiality provisions.

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