RXADVANCE
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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 Online
- Regular Mail or Fax: Download form 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.