



# Clifton Health Department Food Recall Notification



**Public Health**  
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## Food/Drug/Pet Recall: Mylan Institutional, LLC

Mylan today announced that its U.S.-based Mylan Institutional LLC business is conducting a voluntary nationwide recall to the consumer level 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. To date, Mylan has not received any reports of adverse events related to this recall.

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.

This batch was distributed nationwide to wholesalers and retail pharmacies between April 2020 and May 2020. The recalled batch is as follows:

NDC # Material Description Strength Size Lot No Expiry  
67457-813-50 Daptomycin for Injection 500 mg/vial 20 mL vial 7605112 October 2021

Daptomycin for injection is an injectable antibacterial indicated for the treatment of complicated skin and skin structure infections (cSSSI) and staphylococcus aureus bloodstream infections (bacteremia) in adult patients.

Mylan is notifying its distributors and customers by letter and is arranging for return of all recalled products. Consumers/distributors/retailers that have product which is being recalled should stop use/further distribution or dispensing. Wholesalers, retailers and consumers 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.

Consumers with questions regarding this recall can contact Mylan Customer Relations at 800.796.9526 or [customer.service@mylan.com](mailto:customer.service@mylan.com), Monday through Friday from 8 a.m. - 5 p.m. EST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to using these drug products.

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
- . 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



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This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.