July 7, 2020 COM-2020-051

RECALL NOTIFICATION

FDA PUBLICATION DATE:

July 7, 2020

DRUG NAME:

Daptomycin for Injection

COMPANY: Mylan

REASON: Presence of particulate matter

Dear provider of pharmaceutical services,

PharmPix is committed to the health and wellness of our members. The clinical team wants to communicate you with the latest up-to-date information on drug recalls. It is for this reason that we are notifying you that on July 7, 2020 the US Food and Drug Administration (FDA) published a drug recall for the following product(s):

Affected product	NDC	Size	Lot/Expiration
Daptomycin for Injection, 500 mg/vial	67457-813-50	20 mL vial	7605112/ October 2021

Pharmacy required action(s):

- Identify if the product is inventory and immediately stop using and dispensing it.
- Contact all members that in the previous 90 days received the recalled medication.
- Advise patients to contact their physician if they have experienced any problems that may be related to taking or using this product.
- 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.

2 Street 1, Suite 500 Guaynabo, PR 00968 | Tel. 787.522.5252 | Fax 1.866.912.2830 | www.pharmpix.com

Contact information:

- Mylan Customer Relations: 800.796.9526 or customer.service@mylan.com, Monday through Friday from 8 a.m. – 5 p.m. EST.

Remember you can report adverse events related to this or any other drug product at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

- Complete and submit the MedWatch Online Voluntary Reporting Form online.
- Download FDA Form 3500 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.

Additional information can be found at: MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252, extension 137. In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

Regards,

PharmPix Clinical Department

Reference(s):

- Mylan Initiates Voluntary Nationwide Recall of One Lot of Daptomycin for Injection, Due to The Presence of Particulate. U.S. Food and Drug Administration. (2020). Retrieved 7 July 2020, from https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/mylan-initiates-voluntary-nationwide-recall-one-lot-daptomycin-injection-due-presence-particulate.