COMMUNICATION

COM-2022-074

29
DECEMBER
2022

URGENT
PLEASE
REVIEW

Recall Notification

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate the latest up-to-date drug recall information.

U.S. Food & Drug Administration Publication Date:

12/27/2022

Drug Information:

National Drug Code

16729-435-05 AND 16729-434-05

Product Description

DAPTOMYCIN FOR INJECTION 500MG/VIAL AND 350MG/VIAL

Lot Number

R2200232

Expiration Date

JANUARY 2025

Company:

ACCORD HEALTHCARE, INC.

QUESTIONS

Call ACCORD HEALTHCARE INC. at 1.855.869.1081 Monday – Friday from 8:00 a.m. to 5:00 p.m. ET.

Email ACCORD HEALTHCARE INC. at rxrecalls@inmar.com.

Fax ACCORD HEALTHCARE INC. at 1.817.868.5362.

Daptomycin

It is for this reason that we are notifying you that on 12/27/2022 the US Food and Drug Administration published a drug recall for the following product(s): Daptomycin for injection 500mg/vial and daptomycin for injection 350mg/vial.

Pharmacy Required Action:

Identify if the product is in inventory and immediately stop using and dispensing it. The product should be returned to the place of purchase or as directed in the recall notification.

Advise patients that they should not discontinue using the medication without contacting their healthcare provider. Patients experiencing any problem while taking or using this product must contact their physician.

Reason for Recall:

Accord Healthcare, Inc. is voluntarily recalling a single lot of daptomycin for injection 500mg/vial and daptomycin for injection 350mg/vial product contained in cartons to the consumer/user level. Accord received a product complaint report from a hospital pharmacy that vials labeled as “Daptomycin for Injection 500mg/vial” were found in cartons labeled as Daptomycin for Injection 350mg/vial”. The lot and expiration date printed on the outer carton and inner vial are the same and correspond to “Daptomycin for Injection 500mg/vial.”

The administration of daptomycin 500mg/vial to children or patients with renal impairment, the populations most at risk, can potentially lead to serious adverse health consequences such as the ones included in the labeled warnings (e.g., anaphylaxis/hypersensitivity reactions, myopathy and rhabdomyolysis, eosinophilic pneumonia, etcetera).

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- Clinical Department. Our pharmacists will help you.

In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

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urac ACCREDITED Pharmacy Benefit Management Expires 12/01/2025

REFERENCES:
1. U.S. Food and Drug Administration. (2022). Accord Healthcare Inc. Issues Nationwide Voluntary Recall of Daptomycin for Injection 500 mg/vial and Daptomycin for Injection 350 mg/vial Lot # R2200232 Due to Product Mix-Up. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/accord-healthcare-inc-issues-nationwide-voluntary-recall-daptomycin-injection-500-mgvial-and
2. MedWatch: The FDA Safety Information and Adverse Event Reporting Program. https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda

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