COMMUNICATION

COM-2024-025

1
April
2024

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:

03/27/2024

Drug Information:

National Drug Code

69238-2261-3

69238-2261-7

69238-2261-7

69238-2261-5

Product Description

Vancomycin Hydrochloride for Oral Solution, USP, 250mg/5mL

Lot Number

22613003A

22613004A

22613005A

22613005B

Expiration Date

September 2025

Company:

Amneal Pharmaceuticals, LLC

QUESTIONS

Call Amneal at 1.833.582.0812

Monday – Friday from 8:00 a.m. to 5:00 p.m. EST

Vancomycin HCl for Oral Solution

It is for this reason that we are notifying you that on 03.27.2024 the U.S. Food and Drug Administration (FDA) published a drug recall for the following product(s): Vancomycin Hydrochloride for Oral Solution, USP, 250mg/5mL.

Pharmacy Required Action:

Identify if the product is in inventory 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:

Amneal Pharmaceuticals, LLC., is voluntarily recalling four lots of Vancomycin Hydrochloride for Oral Solution, USP, 250mg/5mL, to the consumer level. The recall was initiated due to some bottles may have been overfilled. The recommended maximum daily allowance for this product is up to 2gm/day and patients prescribed a dosing regimen of 500mg/10mL would exceed this daily allowance, which may be harmful to patients with renal insufficiency.

Should a patient receive a dose higher than the recommended daily dose of Vancomycin Hydrochloride for Oral Solution, the patient may experience worsening renal function and electrolyte abnormalities such as high potassium leading to cardiac arrest.

To date, Amneal has not received any reports of serious adverse events related this recall.

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- ext 116. Our pharmacists will help you.

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

PharmPix Drug Recall Communication Number COM-2024-025 April 2024

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REFERENCES:

1. U.S. Food and Drug Administration. (2024). Amneal Pharmaceuticals, LLC. Issues a Nationwide Voluntary Recall of Vancomycin Hydrochloride for Oral Solution USP, 250mg/5mL, Due to the Potential for Some Bottes to be Super Potent Which May be Harmful. Retrieved March 29, 2024, from https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/amneal-pharmaceuticals-llc-issues-nationwide-voluntary-recall-vancomycin-hydrochloride-oral-solution
2. MedWatch: The FDA Safety Information and Adverse Event Reporting Program- Available at: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda

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