COMMUNICATION

2021-047

21 September 2021

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 you with the latest up-to-date drug recall information.

U.S. Food & Drug Administration Publication Date:

09/08/2021

Drug Information:

National Drug Code

65628-206-05

Product Description

Firvanq™ (vancomycin hydrochloride) oral solution 50mg/ml kit

Lot Number

21035

Expiration Date

July 2022

Company:

Azurity Pharmaceuticals, Inc.

QUESTIONS

Call MANUFACTURER at 1-800-461-7449

Monday – Friday from 8:30 a.m. to 5:00 p.m. EDT.

Firvanq™

For this reason, we are notifying you that on 09/08/2021 the US Food and Drug Administration published a drug recall for the following product(s): Firvanq™ (vancomycin hydrochloride) oral solution 50mg/ml kit.

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 that may be related to taking or using this product must contact their physician.

Reason for Recall:

Azurity Pharmaceuticals, Inc. is voluntarily recalling one lot of Firvanq™ (vancomycin hydrochloride) oral solution 50mg/ml kit as some products in the affected lot have been found to incorrectly contain a First Omeprazole (First-PPI) diluent instead of Firvanq™ diluent bottle.

Vancomycin may not be completely solubilized in the FIRST-PPI diluent, which could lead to doses above or below those recommended in the label. There is reasonable probability that the administration of inappropriate doses of oral vancomycin may lead to persistent diarrhea associated with dehydration and electrolyte abnormalities, recurrence of *Clostridium difficile* infection, its progression to severe colitis, colon perforation requiring colectomy, and potentially death.

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. 220. 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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Expires 12/01/2022

REFERENCES:
1. Azurity Pharmaceuticals, Inc. Issues Voluntary Nationwide Recall of One Lot of Firvanq® (Vancomycin Hydrochloride for Oral Solution), Vancomycin 50 mg/mL Kit, Due to a Mix-Up of the Diluent Included in the Kit. U.S. Food and Drug Administration. (2021). Retrieved from https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/azurity-pharmaceuticals-inc-issues-voluntary-nationwide-recall-one-lot-firvanqr-vancomycin.
2. MedWatch Online Voluntary Reporting Form. Accessdata.fda.gov. (2021). Retrieved from https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home.

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