COMMUNICATION

COM-2023-055

26
SEPTEMBER
2023

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:

09.22.2023

Drug Information:

National Drug Code

66689-305-16

Product Description

SUCRALFATE ORAL SUSPENSION 1G/10ML

Batch Number

810300

Expiration Date

OCTOBER 31, 2023

Company:

VISTAPHARM LLC

QUESTIONS

Call INMAR at 1.800.967.5952 Monday – Friday from 9:00 a.m. to 5:00 p.m. ET or email to rxrecalls@Inmar.com

Sucralfate Oral Suspension

It is for this reason that we are notifying you that on 09.22.2023 the US Food and Drug Administration published a drug recall for the following product(s): Sucralfate oral suspension 1g/10mL.

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:

VistaPharm LLC is voluntarily recalling one lot of Sucralfate Oral Suspension, 1g/10mL, to the consumer level, due to *Bacillus cereus* contamination in the product.

There is a reasonable probability that microbial contamination of the oral suspension can result in disseminated, life threatening infections such as endocarditis and necrotizing sofit tissue infections. Immunocompromised individuals are at most risk of these infections.

To date, VistaPharm LLC has not received any reports of adverse events related to this recall. This sucralfate oral suspension lot was distributed nationwide to three distributors by wholesale.

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/.

PharmPix Drug Recall Communication Number COM-2023-055 September 2023

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REFERENCES:

1. U.S. Food and Drug Administration. (2023). VistaPharm LLC Issues Voluntary Nationwide Recall of Sucralfate Oral Suspension, 1g/10mL Due to Microbial Contamination Identified as Bacillus Cereus. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/vistapharm-llc-issues-voluntary-nationwide-recall-sucralfate-oral-suspension-1g10ml-due-microbial
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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