Important Drug Recall Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC23-052-CG
September 26, 2023

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

RECOMMENDATIONS

1. This Sucralfate Oral Suspension Lot was distributed Nationwide to three (3) distributors by wholesale.

2. A Contractor, Inmar, will perform this recall process, which is notifying its distributors by recall packet delivered by FEDEX Next Day Delivery and will receive an email notification as well. In addition, Inmar is arranging for the return of all recalled products. Distributors that have any bottles remaining from Sucralfate Oral Suspension Lot 810300, which is being recalled, should return to Inmar via instructions provided.

3. Consumers with questions regarding this recall can contact Inmar at **1-800-967-5952** or by email to rxrecalls@Inmar.com. Office hours **9am to 5pm EST Monday thru Friday**.

4. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

5. Review your inventory to identify existence of recalled products.

6. Expect patients to visit your pharmacy to deliver recalled products and prepare your pharmacy staff on how to handle the situation.

MC-Rx Pharmacy Services Department

T. (800) 377-1037
1267 Professional Pkwy, Gainesville, GA 30507
T. (787) 286-6032
Call Box 4908, Caguas, P.R. 00726
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FDA U.S. FOOD & DRUG ADMINISTRATION

VistaPharm LLC Issues Voluntary Nationwide Recall of Sucralfate Oral Suspension, 1g/10mL Due to Microbial Contamination Identified as Bacillus Cereus

Summary:

Company Announcement Date:	September 22, 2023
FDA Publish Date:	September 22, 2023
Product Type:	Drugs
Reason for Announcement:	Potential contamination with Bacillus cereus
Company Name:	Potential contamination with Bacillus cereus
Brand Name:	VistaPharm
Product Description:	Sucralfate Oral Suspension 1g/10mL

COMPANY ANNOUNCEMENT

FOR IMMEDIATE RELEASE – September 22, 2023 – Largo, Florida, VistaPharm LLC is voluntarily recalling one (1) lot of Sucralfate Oral Suspension, 1g/10mL, to the consumer level, due to Bacillus cereus contamination in the product.

Risk Statement: In the population most at risk, the immunocompromised population, there is a reasonable probability that microbial contamination of the oral suspension can result in disseminated, life threatening infections such as endocarditis and necrotizing soft tissue infections. To date, VistaPharm LLC has not received any reports of adverse events related to this recall.

The product is used as an antiulcer therapeutic and is packaged in a 16oz (414mL) PET Bottle with NDC 66689-305-16. The affected Sucralfate Oral Suspension lot is number 810300 with an expiration Date of October 31, 2023. The product can be identified with its product name Sucralfate Oral Suspension 1g per 10mL, which the product Lot No 810300 and expiration date of October 31, 2023, at the bottom right side of label. This Sucralfate Oral Suspension Lot was distributed Nationwide to three (3) distributors by wholesale.

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Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online**
- Regular Mail or Fax: **Download form** 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**

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