

Nostrum Issues Voluntary Nationwide Recall of Sucralfate Tablets Within Expiry

Date: 07/14/2025

At Prime Therapeutics, we want to help you receive the best possible care. Visit our drug recall site for details: https://www.primetherapeutics.com/drugrecalls.

About this recall:

On September 30, 2024, Nostrum filed Chapter 11 bankruptcy. As a result, the company has shut down operations and terminated employees at all United States (U.S.) sites. Due to discontinuation of quality activities, Nostrum is initiating a voluntary recall of Sucralfate Tablets, 1 gram (NDCs 29033-0003-01, 29033-0003-05) for all lots within expiry. The company cannot guarantee that this product will meet intended specifications through the product's expiration date.

Sucralfate tablets are used for (1) short-term treatment of active duodenal ulcer and (2) maintenance therapy for duodenal ulcer at reduced doses after healing of acute ulcers.

What this means to you:

The discontinuation of Nostrum's quality program means that the company is unable to guarantee that this product meets the identity, strength, quality and purity characteristics as labeled. Although specific risks to a patient from use of this product cannot be determined, patient risk cannot be ruled out if this product is used. Nostrum has not received any reports of adverse events related to this recall.

Use of any recalled product should stop immediately. Customers with questions regarding this recall can contact Nostrum at recall.com. Consumers should contact their health care provider if they have experienced any problems that may be related to taking this drug.

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: <u>Download form</u> 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-FDA0178.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

For more information regarding this FDA Recall Notification, please refer to the FDA website: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/nostrum-laboratories-inc-issues-voluntary-nationwide-recall-sucralfate-tablets-usp-1-gram-within

FDA contact information for reporting adverse events/quality complaints can be reached online at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home or by calling the FDA at 1-888-INFO-FDA (1-888-463-6332) and then selecting prompt #2.