

*The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.*

Natco Pharma Limited, Pharma Division, Kothur, Ranga Reddy District, Telangana State, India is initiating a recall to the **RETAIL level** for Product Lansoprazole Delayed-Release Capsules USP, 15 mg (ANDA# A203306) batch # 411987 manufactured by Natco Pharma Limited, India and marketed by Rising Pharma Holdings, Inc. USA. Our records indicate that you have purchased the product Lansoprazole Delayed-Release Capsules USP, 15 mg Batch# 411987.

This recall is based on a complaint received by Natco Pharma Limited, Pharma Division, Kothur, Ranga Reddy District, Telangana, India from McKesson Global Procurement and Sourcing. It was reported that 10 bottles had an inadequate induction seal, 17 active spheres sticking to the capsules. 43 capsules stuck together, 2 capsules with holes & exposed drug, 553 with bubbles & blemishes and missing of over coding details on the label for the product Lansoprazole Delayed-Release Capsules USP, 15 mg Batch# 411987.

Natco Pharma Limited, Pharma Division, Kothur, Ranga Reddy District, Telangana, India has conducted a thorough investigation and health hazard assessment. This assessment concluded that Lansoprazole Delayed Release capsules are primarily used to treat hyperacidity of the gastrointestinal tract, inadvertent usage of the defective capsules may potentially lead to subtherapeutic levels of the drug, but no long term effects or serious hazard to the patient is anticipated.

This batch was distributed during the period from 09/13/2023 - 12/21/2023. This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

**PRODUCT NAME:** Lansoprazole Delayed-Release Capsules USP, 15 mg

**NDC NUMBER:** 16571-742-41 (Label) 16571-742-42 (Carton/Shipper Label)

**LOT NUMBER:** 411987

**EXPIRATION DATE:** MAY 2025