

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.

This is to inform you of a product recall by Cipla USA, Inc. for one lot (Lot# 5KA0405) **Fosfomycin Tromethamine Granules for Oral Solution** (Equivalent to 3 Grams of Fosfomycin).

The product is labeled for and marketed by Cipla USA, Inc. bearing the NDC Numbers #69097-579-67.

Out-of-Specification (OOS) result reported at the 18-month long term condition [25°C/60 % RH] stability interval for Fosfomycin Open Ring, Fosfomycin Dimer Tromethamine Adduct, Specified Impurity 3 (RRT approximately 2.2), Any Unspecified Degradation Product, and Total Degradation Products in the Degradation Products test (HPLC).

PRODUCT: Fosfomycin Tromethamine Granules for Oral Solution (Equivalent to 3 Grams of Fosfomycin)

NDC NUMBER: 69097-579-67

LOT NUMBER: 5KA0405

EXPIRATION DATE: December 2026

DATES DISTRIBUTED: May 20, 2025 To June 09, 2025