

*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.*

Out of an abundance of caution, Fagron Compounding Services, LLC d/b/a Fagron Sterile Services, a federally registered 503B Outsourcing Facility located in Wichita, Kansas, is recalling unexpired lots of Compounded Sterile Product Tropicamide 1%/Cyclopentolate 1%/Phenylephrine 2.5%/Ketorolac 0.5%Topical Ophthalmic Solution, 0.5mL Single-Use Syringe delivered to hospitals / clinics in the United States.

FSS is recalling all units of the lot listed below in an abundance of caution. The recall is related to the incorrect bacteriostatic preservative being utilized for product compounding. All final quality testing had reported passing results for Sterility, Endotoxin, Potency, pH and Sub-visual Particulate. Environmental monitoring met specifications and reported no microbial growth.

To date, Fagron Sterile Services has not received any complaints or reports of adverse events associated with the lot being recalled. We have a primary root cause and have known immediate corrective actions but, as part of our thorough Quality system, we are continuing to assess other actions we can take to continue to ensure high quality supply for our customers.

This is an isolated incident and there are no other current lots or products affected. We are working in conjunction with the U.S. Food and Drug Administration (FDA) regarding this voluntary recall and this communication has been approved by the FDA.

PRODUCT: Tropicamide 1%/Cyclopentolate 1%/Phenylephrine 2.5%/Ketorolac 0.5%Topical Ophthalmic Solution, 0.5mL Single-Use Syringe

LOT NUMBER: C274-000047958

ITEM NUMBER: 2000082

MANUFACTURING DATE: 08/21/2025

EXPIRY DATE: 12/19/2025