

*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.*

Fagron Compounding Services, LLC dba Fagron Sterile Services, a federally registered 503B Outsourcing Facility located in Wichita, Kansas, is recalling the following lots of unexpired sterile ophthalmic eye drops delivered to hospitals / clinics in the US.

It should be noted that FSS offers this topical formulation in two delivery devices – a dropper bottle and a syringe (which does not include a needle or other mechanism to pierce the skin, cornea or sclera). Aside from the delivery device, all other aspects of the formulation, dosing and drug delivery are exactly the same.

This, lot-specific, recall is solely related to label inaccuracy. The affected lot labels state that the container is a 0.5mL single-use syringe rather than a 5mL multi-dose dropper bottle. All other information on the label is correct, including the active ingredients/concentrations, inactive ingredient/concentrations, and instructions “for topical ophthalmic use only”, protect from light and refrigerate at 2-8°C. This label inaccuracy was identified as part of an investigation related to a customer complaint stating the label of a dropper bottle container stated that the container was a single-use syringe. The root cause has been identified and remediated. Corrective actions have been implemented to prevent such instances in the future and ensure the highest quality products are delivered to our customers.

This is an isolated incident and there are no other current lots or products affected. In addition, this recall has been communicated to the U.S. Food and Drug Administration.

<b>Lot Number</b>	<b>Item Description</b>	<b>Item Number</b>	<b>Manufacturing Date</b>	<b>Expiry Date</b>
C274-000033372	Tropicamide 1% (10mg/mL), Cyclopentolate 1% (10mg/mL), Phenylephrine 2.5% (25mg/mL), Ketorolac 0.5% (5mg/mL) Topical Ophthalmic Solution, 5 mL in 5 mL Dropper Bottle, Multi-Dose	2000081 (NDC 71266-8240-05)	09-19-2023	01-17-2024
C274-000033764	Tropicamide 1% (10mg/mL), Cyclopentolate 1% (10mg/mL),	2000081 (NDC 71266-	10-09-2023	02-06-2024

Phenylephrine 2.5%                      8240-05)  
(25mg/mL), Ketorolac 0.5%  
(5mg/mL) Topical Ophthalmic  
Solution, 5 mL in 5 mL  
Dropper Bottle, Multi-Dose