

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.

Apotex Corp. is recalling three (3) batches of **Ketorolac Tromethamine OP/SOL 0.5% 5mL** (batches VA0444, VA4608 and TZ7016) to the **Retail/Pharmacy level**. This recall is being initiated out of an abundance of caution. It follows the discovery of atypical weight loss in individual bottles from batch VA0444 that were sored horizontally. While this batch met all quality specifications at the time of release – and continues to meet all filed and approved stability test specifications - the company has decided to recall the below batches. The recall is also extended to include batches VA4608 and TZ7016 as they were made with the same combination of components as batch VA0444.

Based on the completed health hazard assessment and test data conducted on the bottles with atypical weight loss, the observed atypical individual weight loss results will not have significant adverse effects on the safety and efficacy of the product and thus would not affect the risk benefit profile of the drug product if used before expiry date. The details for the batches being recalled are listed below.

Product	Strength	Pack Size	NDC	UPC on Bottle	UPC on Carton	Batch Number	Expiry Date (mm/yyyy)	First Date of Sale (mm/dd/yyyy)	Last Date of Sale (mm/dd/yyyy)
Ketorolac Tromethamine Ophthalmic Solution	0.5%	5 mL	60505-1003-1	(01)0(03)60 505100316	3605051 00316	VA0444	01/2026	02/21/2024	04/05/2024
						VA4608	01/2026	03/15/2024	07/25/2024
						TZ7016	12/2025	01/16/2024	01/23/2024