

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.

FDC Limited, is initiating a recall on Timolol Maleate Ophthalmic Solution USP, 0.5% (ANDA 077259) batch number 083H008, 083G003, 083I013 and 083J017 manufactured at FDC Limited located in Maharashtra, India and marketed by Rising Pharma Holdings, Inc. USA. Our records indicate that you have purchased this product, during the dates it was marketed.

This recall is based on complaints received from patients by FDC Limited wherein it is reported that the patients are unable to get the product solution out of the bottle as the spike of the cap was lodged in the nozzle of product bottle.

FDC Limited has conducted preliminary investigation and health hazard assessment. This assessment concluded that it is unlikely that this issue can cause any adverse health consequences to the patients and no long-term risk can be stipulated. These batches were distributed between October 2023 to April 2024.

Product Name	NDC(s)	Lot(s) /	Exp. date	Distributed Quantity	Distribution dates
Timolol maleate ophthalmic solution USP, 0.5%	64980-514-05	083H008	07/2025	116112 units	10/31/2023 - 01/02/2024
Timolol maleate ophthalmic solution USP, 0.5%	64980-514-05	083G003	06/2025	118104 units	11/10/2023-12/30/2023
Timolol maleate ophthalmic solution USP, 0.5%	64980-514-15	083I013	08/2025	29784 units	01/18/2024 – 03/13/2024
Timolol maleate ophthalmic solution USP, 0.5%	64980-514-05	083J017	09/2025	118104 units	02/17/2024 – 04/10/2024