

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 that Sun Pharmaceutical Industries, Inc. has initiated a recall in response to Out of Specification (OOS) results reported in Unit Dose Content Test in Loteprednol Etabonate Ophthalmic Suspension, 10 mL and 15 mL, Batch BAC0108A and Batch BAC0285A during shelflife station (25°C/40%RH) analysis, respectively. As both of these batches are expired, other batches of 10 mL and 15 mL are considered for recall.

Sun Pharmaceutical Industries, Inc. initiated shipment of this product on September 9, 2021.

Product Name	Package Description	Lot Number	NDC Number	Expiration Date
Loteprednol Etabonate Ophthalmic Suspension 5 mg/mL (0.5%)	10 mL bottle in 1 carton	BAC0334A	62756-232-55	06/2023
Loteprednol Etabonate Ophthalmic Suspension 5 mg/mL (0.5%)	10 mL bottle in 1 carton	BAC0532A	62756-232-55	11/2023
Loteprednol Etabonate Ophthalmic Suspension 5 mg/mL (0.5%)	10 mL bottle in 1 carton	BAD0407A	62756-232-55	08/2024
Loteprednol Etabonate Ophthalmic Suspension 5 mg/mL (0.5%)	10 mL bottle in 1 carton	BAD0425A	62756-232-55	08/2024
Loteprednol Etabonate Ophthalmic Suspension 5 mg/mL (0.5%)	15 mL bottle in 1 carton	BAC0335A	62756-232-56	06/2023
Loteprednol Etabonate Ophthalmic Suspension 5 mg/mL (0.5%)	15 mL bottle in 1 carton	BAC0533A	62756-232-56	10/2023
Loteprednol Etabonate Ophthalmic Suspension 5 mg/mL (0.5%)	15 mL bottle in 1 carton	BAD0148A	62756-232-56	03/2024
Loteprednol Etabonate Ophthalmic Suspension 5 mg/mL (0.5%)	15 mL bottle in 1 carton	BAD0320A	62756-232-56	07/2024