

*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 notice is from Sun Pharmaceutical Industries, Inc to inform you of a product recall involving Budesonide Inhalation Suspension 1mg/2ml.

This recall has been initiated in response to a product quality complaint reported for black/brown specs and particles within the ampoule solution for lot BAG0074A. The Health Hazard Evaluation concluded that these particles are visible to naked eyes, consumption is unlikely and are not expected to be inhaled along with the suspension, and therefore, no impact on patient safety is anticipated.

The lot complied with all of the established product specifications at the time the product was released for distribution.

Sun Pharmaceutical Industries, Inc. initiated shipment of this product between June 30, 2025 and September 26, 2025.

PRODUCT: Budesonide Inhalation Suspension 1mg/2ml, 30 count

NDC NUMBER: 47335-633-49

LOT NUMBER: BAG0074A

EXPIRATION DATE: 1/31/2027