

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.

As a precautionary measure, Lupin Pharmaceuticals, Inc. is initiating a recall of lots: **G201822, Expiry, January 2024, G201823, Expiry, January 2024, G201824, Expiry, January 2024** of Desloratadine Tablets USP, 5mg to **retail** level. These lots are being recalled due to N-Nitroso Desloratadine impurity result exceeding acceptable intake limit.

N-Nitroso Desloratadine impurity falls into the potency category 3. Considering the levels of the impurity under discussion, potential health hazards upon continuous and/or long-term usage cannot be completely ruled out. However, the health risk associated to the exposure varies from person to person based on concurrent medication/dose regimen.

The recalled lots were distributed between May 2022 and September 2022 to wholesalers, distributors, drug chains, mail order and supermarkets (food) nationwide.

Desloratadine Tablets USP are supplied as:

Product label:

Strength	Lot	Expiry	NDC	Description
5mg	G201822 (100's HDPE)	Jan. 2024	68180-153-01	Light blue film coated, circular, biconvex tablet debossed 'LU' on one side and 'S71' on other side.
	G201823 (100's HDPE)	Jan. 2024	68180-153-01	
	G201824 (500's HDPE)	Jan. 2024	68180-153-02	