

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.

Lupin Pharmaceuticals, Inc. is initiating a recall of lots A200816, Expiry: January 2024 and A201248, Expiry: March 2024 of Rifampin Capsules USP, 150mg and lot A200817, Expiry: January 2024 of Rifampin Capsules USP, 300mg to retail level. These lots are being recalled due to out of specification result observed in assay testing of all above lots and related substance testing (N-Methyl Rifampin impurity) in lot A200816, Expiry: January 2024 during stability study. The reduction in the assay content may result in slight decrease in therapeutic effect (sub-therapeutic response). The toxicological properties of N-Methyl Rifampin impurity have not been extensively studied; thus, the health hazards cannot be conclusively assessed. The recalled lots were distributed between February 2022, and June 2022 to wholesalers, distributors, and mail order pharmacies and supermarkets (food) nationwide.

Rifampin Capsules USP, 150mg and 300 mg are supplied as:

Strength	Lot	Count	Expiry	NDC	Description
150 mg	A200816		01/2024		Rifampin Capsules USP, 150 mg are size '2' capsules having dark red cap, imprinted with "LU" in white ink and light red body, imprinted with "E01" in white ink, containing reddish brown powder.
	A201248	30	03/2024	68180-658-06	Rifampin Capsules USP, 300 mg are size '1' capsules having dark red cap, imprinted with "LU" in white ink and light red body, imprinted with "E02" in white ink, containing reddish brown powder.
300 mg	A200817	count	01/2024	68180-659-06	