

*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 lot M300464, Expiry: June 2025 of clomiPRAMINE Hydrochloride Capsules USP 25 mg (100's) to the retail level. This lot is being recalled due to an out of specification ("OOS") result observed in a degradation product test (any unspecified degradation product) during retention sample testing at expiry.

The pill is described as a size '2' hard gelatin capsules with melon opaque cap imprinted with 'LU' in black ink and ivory opaque body imprinted with 'C35' in black ink containing white granular powder.

The potential health hazard related to the marginal increase of the unspecified degradant could not be conclusively predicted; however, a comprehensive evaluation is ongoing.

The recalled lot was distributed between November 2023 to July 2024 to the wholesalers/distributors and drug chain nationwide.

PRODUCT: clomiPRAMINE Hydrochloride Capsules USP 25 mg (100's)

NDC NUMBER: 68180-492-01

LOT NUMBER: M300464

EXPIRATION DATE: June 2025