

*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 M300442, 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 degradation product test (any unspecified degradation product) during 18-month long term stability study.

It is described as 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 health hazard related to marginal increase of unspecified degradation could not be conclusively predicted as further evaluation is ongoing.

The recalled lot was distributed between August 2023 to January 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: M300442

EXPIRATION DATE: June 2025