

*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 is to notify you that Zydus Pharmaceuticals (USA) Inc. ("Zydus"), is recalling Chlorpromazine Hydrochloride Tablets, USP 10 mg.

This recall has been initiated due to an observed OOS (Out of Specification) of Nitrosamine Drug Substance-Related Impurities (NDSRis) in the drug product Chlorpromazine Hydrochloride Tablets USP 10mg. Consumption of the affected product may carry a potential risk of carcinogenicity, which is considered a general characteristic of Nitrosamine compounds. However, due to limited research and literature on this molecule, conducting an assessment is challenging.

The product was shipped to our customers from May 2024 to Feb 2025.

PRODUCT: Chlorpromazine Hydrochloride Tablets, USP 10 mg, 100's Count

NDC NUMBER: 70710-1129-1

LOT NUMBER: Z400069

EXPIRATION DATE: 12/2025

DISTRIBUTION DATES: 05/2024 - 02/2025