

PRODUCT RECALL: Benzonatate Capsules USP 100 mg

Urgent Drug Recall

This official communication is to notify you that Zydus Pharmaceuticals (USA) Inc., is voluntarily recalling one lot of the drug product mentioned below at the retail level.

Product	NDC Number	Lot Number	Expiry Date	Count	Distribution Start Date	Distribution End Date
Benzonatate Capsules, USP 100 mg	68382-247-01	M302838	March 2025	100's count	06/08/2023	09/22/2023

Zydus Pharmaceuticals (USA) Inc. has decided to initiate a voluntary recall of one lot of Benzonatate Capsules USP 100 mg based on the communication received from a repackager American Health Packaging (AHP) about initiation of a product recall of repackaged product due to an out of specification result. The assay result of the repackaged lot observed for assay content was found above specification. Please note that the Zydus lot number M302838 of Benzonatate Capsules, USP 100 mg meets the FDA approved release specification. However, out of an abundance of caution, and our continuous focus on patient safety, we are proactively recalling this referenced lot at the Retail Level as the repackaged lot is found to be out of specification.

