

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.

Teva Pharmaceuticals USA, Inc. (TEVA) is initiating a nationwide recall of the below four (4) lots of Metoclopramide Tablets USP, 5mg to the RETAIL LEVEL. The product in this recall is distributed under the Teva Pharmaceuticals USA, Inc. label. These lots are being recalled as a safety precaution because, to date, a single Buspirone Hydrochloride Tablet, USP (10 mg) was discovered in each of two individual sealed bottles of Metoclopramide Tablets USP, 5mg lot # 8636085. The clinical concern regarding use of the recalled lot is lack of effect or lack of efficacy and/or potential for an adverse event(s). To date, TEVA has received no relevant complaints for drug ineffectiveness, lack of effect or lack of efficacy. Teva's health hazard assessment concluded that the main potential consequences are omission of the intended dose or inadvertent ingestion of a foreign tablet. While accidental administration of a single buspirone tablet would not be expected to result in clinically significant consequences for most patients, serious adverse outcomes cannot be excluded in susceptible individuals, including patients with buspirone hypersensitivity, patients receiving interacting medications (e.g., MAO inhibitors or serotonergic agents), or patients with relevant hepatic or renal impairment. Therefore, considering the most susceptible patient population, the severity of the hazard was assessed as severe, the likelihood of the harm occurrence is remote. Consequently, the overall risk of harm in patient population is considered to be medium.

This recall is being made with the knowledge of the U.S. Food and Drug Administration.

Metoclopramide Tablets, USP 5mg

NDC	Lot #	Exp. Date	Size
0093- 2204-01	8634085	07/2027	100 count bottle
0093- 2204-01	8635085	07/2027	100 count bottle

0093- 2204-01	8636085	07/2027	100 count bottle
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Metoclopramide Tablets, USP 5mg

NDC	Lot #	Exp. Date	Size
0093- 2204-05	8633085	07/2027	500 count bottle