

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.

On September 26th, Padagis LLC initiated a retail/pharmacy level recall of one batch of GYNAZOLE-1® (Butoconazole Nitrate Vaginal Cream USP, 2%) 5.8g in the marketplace. Customers that may have further distributed this product are requested to contact their customers and notify them immediately of this product recall.

Batch 164185 is being recalled as that batch was manufactured using *Hydrophilic* Colloidal Silica rather than *Hydrophobic* Colloidal silica as required by the manufacturing process. Presently, there have been no associated adverse event or lack of efficacy reports for the batch. Use of the affected batch is not expected to pose a patient safety risk.

Product: GYNAZOLE-1® (Butoconazole Nitrate Vaginal Cream USP, 2%), 5.8g

NDC: 45802-0396-01

Strength: 2%

Package Size: 5.8 grams

Batch Number: 164185

Exp: 04/2024

Distribution Dates: 09/25/2022 - 07/11/2023