

The Board of Pharmacy has received notice of the following product market withdrawal:

Product: Nitroglycerin Lingual Spray

NDC: 45802-210-02

Strength: 400 mcg/Spray

Package Size: 12 grams

Batch Numbers: 150892 exp.10/22, 153199 exp. 02/23, 156041 exp. 04/23 Manufactured By: Padagis Israel Pharmaceuticals Ltd., an affiliate of Padagis US, LLC.

Please note the referenced drug product batches are labeled with Perrigo trade dress.

Distribution Dates: 08/25/2021-12/16/2021

Padagis US LLC is initiating a consumer level recall of three batches of Nitroglycerin Lingual Spray, 400mcg/Spray 12g Bottle currently in the marketplace. These batches are being recalled due to possible failure of the product to properly dispense medication.

There is the potential for some units to contain a disassembled pump, affecting the ability to dispense medication. There is a remote probability that medically reversible, transient and/or serious adverse health consequences could occur in patients experiencing angina pectoris who are unable to use their device. To date, Padagis has not received any adverse event reports associated with the issue.

Please note, the referenced drug product batches are labeled with Perrigo trade dress.

This action is being taken with the knowledge of the FDA and is being issued to the consumer level.

The Board of Pharmacy strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.