COMMUNICATION

2022-001

05 JANUARY 2022

URGENT PLEASE REVIEW

Recall Notification

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate you with the latest up-to-date drug recall information.

U.S. Food & Drug Administration Publication Date:

12/27/2021

Drug Information:

National Drug Code

45802-0210-02

Product Description

Nitroglycerin lingual spray

Lot Number

150892, 153199, 156041

Expiration Date

Lot #150892 – October 2022

Lot #153199 – February 2023

Lot #156041 – April 2023

Company:

Padagis US LLC

QUESTIONS

Call Sedgwick at 888-266-7912

Monday – Friday from 8:00 a.m. to 5:00 p.m. EST.

Email: padagis5665@sedgwick.com

Nitroglycerin Lingual Spray

It is for this reason that we are notifying you that on 12/27/2021 the US Food and Drug Administration published a drug recall for the following product: Nitroglycerin lingual spray.

Pharmacy Required Action:

Identify if the product is in inventory and immediately stop using and dispensing it. The product should be returned to the place of purchase or as directed in the recall notification.

Advise patients that they should not discontinue using the medication without contacting their healthcare provider. Patients experiencing any problem while taking or using this product must contact their physician. Patients who have this product should contact their healthcare provider for an alternate replacement before returning the recalled product.

Reason for Recall:

Padagis US LLC has issued a voluntary nationwide recall to the consumer/user level of 3 lots of nitroglycerin 12g spray bottle. This product is being recalled from the market due to a complaint received that a unit may not dispense. There is a remote risk that the product may not properly dispense medication to patients in the event of a malfunction of their dispensing unit.

If the product does not deliver the appropriate amount of nitroglycerin, the patient will likely continue to experience chest pain. The label advises that if relief is not obtained after 3 doses over 15 minutes the patient should promptly seek medical attention. To date, Padagis has not received any reports of adverse events related to this recall.

Padagis is notifying its distributors and customers by express package delivery service as well as electronic mail and is arranging for return of all recalled products.

Remember you can report adverse events related to this or any other drug product at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

Complete and submit the MedWatch Online Voluntary Reporting Form online.

Download FDA Form 3500 or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

Additional information can be found at: MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252- Clinical Department. Our pharmacists will help you.

In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

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Pharmacy Benefit Management
Expires 12/01/2022

REFERENCES:
1. U.S. Food and Drug Administration. (2021). Padagis Issues Voluntary Nationwide Recall for Nitroglycerin Lingual Spray Due to a Possible Defective Delivery System. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/padagis-issues-voluntary-nationwide-recall-nitroglycerin-lingual-spray-due-possible-defective
2. MedWatch: The FDA Safety Information and Adverse Event Reporting Program. https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda

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