COMMUNICATION

COM-2023-029

24
MAY
2023

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 the latest up-to-date drug recall information.

U.S. Food & Drug Administration Publication Date:

05/19/2023

Drug Information:

National Drug Code

52083-0655-01

Product Description

G-SUPRESS DX PEDIATRIC DROPS 2.5MG-5MG-50 MG/ML

Lot Number

D20911

Expiration Date

OCTOBER 2025

Company:

NOVIS PR LLC

QUESTIONS

Call Novis PR LLC at 787.767.2072 Monday – Friday from 8:00 a.m. to 4:00 p.m. ET.

G-Supress DX Pediatric Drops

It is for this reason that we are notifying you that on 05.19.2023 the US Food and Drug Administration published a drug recall for the following product(s): G-Supress DX Pediatric Drops 2.5-5-50 mg/mL.

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.

Reason for Recall:

Novis PR LLC is voluntarily recalling LOT D20911 of G-Supress DX Pediatric Drops to the consumer level because some cartons of the product have been found to be contain incorrect product inside. Incorrect product inside is an anesthetic/analgesic and not a brand of Novis PR LLC.

The anesthetic/analgesic product contains 60% ethyl alcohol and 5% benzocaine. The risk of serious adverse events exists with a product containing alcohol, such as alcohol toxicity. Moreover, the product contains benzocaine but does not include a Warning for methemoglobinemia which is a condition in which too little oxygen is delivered to your cells that can be life-threatening.

To date, Novis PR LLC has not received any reports of adverse events or injuries related to this recall.

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/.

pharmpix
POWERED BY ONEARK

urac
ACCREDITED
Pharmacy Benefit Management
Expires 12/01/2025

REFERENCES:
1. U.S. Food and Drug Administration. (2023). Novis PR LLC. Novis PR LLC Issues Voluntary Recall of G-Supress DX Pediatric Drops Due to Incorrect Packaging. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/novis-pr-llc-issues-voluntary-recall-g-supress-dx-pediatric-drops-due-incorrect-packaging
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

2 Street 1, Suite 500
Guaynabo, PR 00968
Tel. 787.522.5252
Fax 866.912.2830
www.pharmpix.com
FRM-CL-000126-000

CLINICAL PEARLS
BY PHARMPIX