

Novis PR LLC Issues Voluntary Recall of G-Supress DX Pediatric Drops Due to Incorrect Packaging

Novis PR LLC

(787)767-2072

05/15/23– San Juan, PR, Novis PR LLC is voluntarily recalling Lot D20911 Exp 10/25 of G-Supress DX Pediatric Drops to the consumer level. Some cartons of the product have been found to contain incorrect product inside. Incorrect product inside is an anesthetic/analgesic and not a brand of Novis PR LLC.

Anesthetic/Analgesic product contains 60% ethyl alcohol and 5% benzocaine. There is a probability of serious adverse events with a product containing alcohol including alcohol toxicity. Infants and young children are prone to profound hypoglycemia, coma, and hypothermia from ingesting relatively small amounts of ethanol, and deaths have been reported. Furthermore, 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.

G-Supress DX Pediatric Drops is a cough suppressant, expectorant and nasal decongestant used for the temporary relief of the common cold symptoms, supplied in 1 oz. bottles packaged in a carton box. Oral anesthetic/analgesic liquid used for temporary relief for the mouth and gums supplied in 0.5 fl. oz. (15 mL) bottles. Lot D20911 was distributed among pharmacies in Puerto Rico.

Novis PR LLC is notifying its distributors and customers by email and telephone calls and arranging return of recalled lot. Consumers/distributors/retailers that have affected lot should stop using and return to place of purchase.

Consumers with questions regarding this recall can contact Novis PR LLC at 787-767-2072 Monday through Friday from 8:00AM – 4:00 pm EST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm 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

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

NDC 52083-655-01

G-SUPRESS DX

PEDIATRIC DROPS

Compare to Supress® DX

**COUGH SUPPRESSANT
EXPECTORANT
NASAL DECONGESTANT**

Cherry Flavor Sugar & Alcohol FREE

NET CONTENT: 30 mL (1 FL. Oz.)



Drug Facts Active ingredients (in each 1 mL) Dextromethorphan HBr, 5 mg, Cough Suppressant Guaifenesin, 50 mg, Expectorant Phenylephrine HCl, 2.5 mg, Nasal Decongestant	Purposes Cough Suppressant Expectorant Nasal Decongestant
Uses ■ helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive ■ temporarily relieves: ■ nasal congestion due to hay fever or other upper respiratory allergies (allergic rhinitis) ■ cough due to minor throat and bronchial irritation as may occur with the common cold	Directions ■ do not use more than 6 doses in any 24-hour period ■ repeat every 4 hours ■ measure with the dosage device provided. Do not use with any other device ■ Children 2 to under 6 years of age: 1 mL ■ Children under 2 years of age: consult a doctor.
Warnings ■ Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.	Other information ■ Tamper Evident Feature: Do not use if cap seal is torn, broken or missing ■ Store at controlled room temperature 15-30°C (59-86°F)
	Inactive ingredients ■ citric acid, FD&C Red 40, flavor, glycerin, methylparaben, potassium sorbate, propylene glycol, propylparaben, purified water, sodium citrate, sucralose
	Questions or comments? call weekdays from 8 am to 4 pm AST at 1.787.767.2072

Manufactured in the USA for Kramer Novis, San Juan, PR 00917. www.kramernovis.com

RETAIN CARTON FOR FULL PRESCRIBING INFORMATION Rev. 05/22