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

Novis PR LLC
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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.