Children's Guaifenesin Grape Liquid and Guaifenesin DM Cherry Liquid by Perrigo Company: Recall - Potential Defect with Dosage Cup

Including store brands:

- Sunmark
- Rite-Aid
- Topcare
- Kroger
- GoodSense
- Dollar General
- Care One
- CVS

AUDIENCE: Consumer

ISSUE: Perrigo Company announced that, following the recent recall of certain dosing cups by its supplier, it has initiated a voluntary product recall in the US to the retail level of 2 batches of its children's guaifenesin grape liquid (100mg/5 mL) and 3 batches of its children's guaifenesin DM cherry liquid (100mg guaifenesin and 5mg dextromethorphan HBr/ 5 ml) sold in 4 oz. bottles with dosage cup in a box under multiple store brand product names. Some packages contain an oral dosing cup with incorrect dose markings. See the press release for affected label and lot numbers.

At risk populations such as those who are poor metabolizers of dextromethorphan may experience an overdose by a factor of 3, if incorrect measuring levels are used.

Consumers should be aware that an overdose of Guaifenesin DM may cause hyper excitability, rapid eye movements, changes in muscle reflexes, ataxia, dystonia, hallucinations, stupor, and coma. Other effects have included nausea, vomiting, tachycardia, irregular heartbeat, seizures, respiratory depression, and death. Small children who are poor metabolizers of dextromethorphan and use the product regularly over a period of several days at the mistaken dose, may develop cumulative toxicity. Moreover, adverse reactions to guaifenesin when given in high or excessive dosage may include nausea/vomiting, diarrhea, and/or abdominal pain. Therefore, an extreme overdose in an at risk population may need medical intervention, but in most cases adverse health consequences are temporary and reversible.

BACKGROUND: These recalled products are sold by distributors nationwide and distributed through retail stores.

RECOMMENDATION: Gastric decontamination is recommended after acute ingestion of greater than 10 mg/kg, if administered soon after ingestion.

Consumers that have product with the corresponding labels and batch numbers listed in the Press Release should discard the dosing device and product and may call Perrigo, toll free,Monday through Friday from 8:00 AM to 10:00 PM EST, at 1-888-345-0479, or visit mucusreliefrecall.com. Consumers should contact their physician or healthcare provider if they have any questions, or if they or their children experience any problem that could possibly be related to this drug product.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- Download form 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

Read the MedWatch safety alert, including a link to the press release, at:

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm481563.htm