AMERICAN HEALTH CARE

DRUG PRODUCTS & SAFETY NEWS

Children's Guaifenesin Liquid Recall

January 11, 2016

Perrigo Company announced that, following the recent recall of certain dosing cups by its supplier, it has initiated a voluntary product recall in the U.S. to the retail level. The recall includes 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) that are 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. 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.

These OTC products are indicated for helping to loosen phlegm (mucus), thin bronchial secretions, and making coughs more productive, as well as in the case of the DM product to temporarily relieve coughs due to minor throat irritations, the intensity of coughing, and the impulse to cough.

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 at risk populations may need medical intervention, but in most cases adverse health consequences are temporary and reversible. Gastric decontamination is recommended after acute ingestion of greater than 10 mg/kg, if administered soon after ingestion.

These recalled products are sold by distributors nationwide and distributed through retail stores. 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 any adverse events or side effects related to the use of this product and/or quality problems to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- ✓Complete and submit the report online: www.fda.gov/MedWatch/report.htm
- ✓Complete and return a form by mail (address on the pre-addressed form) or fax (1-800-FDA-0178).

[Call 1-800-332-1088 to request a reporting form or download a form at http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm.]

For more information or for recalled batch information, visit http://www.fda.gov/Safety/Recalls/ucm481411.htm

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