Reese Pharmaceutical Company OTC Products: Recall - Mislabeled Guaifenesin Tablets

U.S. Food & Drug Administration

AUDIENCE: Consumer, Pharmacist

ISSUE: Reese Pharmaceutical Company has voluntarily recalled lot# 091612 only in 60-count size bottles identified under four different brand names: Refenesen Expectorant (guaifenesin 200 mg tablets), Select Brand Mucus Relief Expectorant (guaifenesin 200 mg), QC Medifin Expectorant (guaifenesin 200 mg), and Leader Cough Tabs Expectorant (guaifenesin 200 mg) because cold decongestant tablets (containing Acetaminophen 325 mg, Phenylephrine 5 mg & Chlorpheniramine Maleate 2 mg) were mislabeled as containing only 200mg Guaifenesin tablets.

BACKGROUND: The mislabeled product does not warn consumers that Acetaminophen may cause liver damage. Ingesting high doses of Acetaminophen can potentially cause severe liver damage. The likelihood of acute liver damage is higher among consumers with pre-existing liver disease and those who drink three or more alcoholic drinks per day. Overdose may specially occur if consumers are also taking other cold/cough products that contain Acetaminophen in addition to the mislabeled product. Contraindications for Phenylephrine are high-blood pressure, poor blood flow to the extremities, and patients on antidepressants known as MAO Inhibitors. Furthermore, products that contain Phenylephrine should be used with caution in patients with high blood pressure, diabetes, heart disease, increased intraocular pressure, hyperthyroidism, or enlarged prostate. Consumers who are allergic to any of the ingredients or who have narrow angle glaucoma, or are pregnant or nursing mothers, also should not take the product.

RECOMMENDATION: 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.htm [1]
- Download form [2] 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

[12/08/2010 - Press Release [3] - Reese Pharmaceutical]

SOURCE [4]

Source URL (retrieved on *12/22/2014 - 4:46pm*):
http://www.mdtmag.com/news/2010/12/reese-pharmaceutical-company-otc-products-recall-mislabeled-guaifenesin-tablets

Links:
[1] http://www.fda.gov/MedWatch/report.htm
[2] http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm
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