

Alert : Side Effects From Maalox Product Mix-Ups

Contributed by Medianowonline Newsnetwork

Maalox product maker agrees to name change to avoid confusion

SILVER SPRING, Md., Feb. 18- The U.S. Food and Drug Administration today warned consumers about the potential for serious side effects from mistakenly using Maalox Total Relief instead of other Maalox products. The two products are intended for the relief of different symptoms and contain different active ingredients.

Maalox Total Relief is an upset stomach reliever and anti-diarrheal medication, while traditional Maalox liquid products Maalox Advanced Regular Strength and Maalox Advanced Maximum Strength are antacids. Both Maalox Total Relief and Maalox are made by Novartis Consumer Health Inc. (NCH) and are available without a prescription as over-the-counter liquid medications.

The maker of Maalox brand products has agreed to change the name of Maalox Total Relief to one that does not include the word "Maalox" and will change the drug's packaging to avoid further confusion.

"Maalox Total Relief and Maalox are not interchangeable and shouldn't be used in place of each other," says Carol Holquist, R.Ph., director of FDA's Division of Medication Error Prevention and Analysis. "Consumer confusion and incorrect product use due to name confusion are serious public health issues. We appreciate Novartis' efforts to work collaboratively with FDA and their decision to remedy this situation to avoid any confusion over Maalox products in the future."

Maalox Total Relief's active ingredient (bismuth subsalicylate) is chemically related to aspirin and may cause similar harmful side effects such as bleeding. As such, Maalox Total Relief is not appropriate for individuals with a history of gastrointestinal ulcer disease or a bleeding disorder. Maalox Total Relief also should not be taken by children and teens if they are recovering from a viral infection, nor by individuals who are taking certain medications including: oral antidiabetic drugs (OADs), anticoagulation (thinning the blood) drugs such as warfarin (Coumadin) and clopidogrel (Plavix), non-steroidal anti-inflammatory drugs (NSAIDs), and other anti-inflammatory drugs.

Packaging and labeling of Maalox Total Relief and traditional Maalox Advanced Regular Strength and Maalox Advanced Maximum Strength are very similar and easily confused. Due to this confusion, NCH has agreed to:

- Change the name of Maalox Total Relief to one that does not include the root name Maalox as well as change the product label design;
- Conduct an educational campaign with outreach to healthcare professionals and consumers regarding different Maalox products and ways to select the appropriate Maalox brand product; and,
- Actively monitor and report adverse events associated with the use of Maalox brand products.

"The FDA is concerned about the public health impact of medication mix-ups for products that have the same names or portions of the same name, but contain different active ingredients," said Ms. Holquist. "We want companies to consider the potential for name confusion when choosing names for their drugs."

The renamed product is expected to begin selling in September 2010. Until that time, FDA is advising consumers and healthcare professionals to carefully check the labels of all Maalox products to ensure the appropriate product is being selected for the patient's symptoms.

Any Maalox side effects or other product problems should be reported to FDA's MedWatch Adverse Event Reporting program at 1-800-332-1088.