Drug errors associated with Maalox

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Maalox is a well-recognized brand name that healthcare professionals associate with nonprescription or OTC antacid drug products containing the active ingredients aluminum hydroxide, magnesium hydroxide, and simethicone. However, the Food & Drug Administration wants to alert healthcare professionals that Maalox Total Stomach Relief (an OTC upset stomach reliever/antidiarrheal drug product) contains the active ingredient bismuth subsalicylate. In fact, each tablespoonful contains 525 mg of the agent. It is important to remember the difference in this formulation compared with other Maalox products because salicylates can have a significant impact on patient safety, depending on consumer health status and concomitant drug therapy.

Following the introduction of Maalox Total Stomach Relief, the FDA was notified of several medication errors involving confusion between this product and the other currently marketed Maalox brands. The confusion stems from the limited awareness of the new formulation and its product differences. Additionally, the inclusion of labeling such as "New" and "Maximum Strength" used to describe Maalox Total Stomach Relief can be confusing. Maalox Total Stomach Relief is not a more potent formulation of the Maalox product labeled "Regular Strength" but actually contains a different active ingredient.

Photo: Jim Shive

Another contributing factor to this confusion is the similar packaging and labeling of the Maalox brand product line. The liquid Maalox products are packaged in white plastic containers of the same size and shape. Although the color of the cap on each formulation differs, the trade name "Maalox" is presented in the same manner (font type, orientation on the label, etc.) on all products. These factors highlight the importance of reading the labeled ingredients in each bottle to ensure proper product selection.

Although Maalox Total Stomach Relief contains a salicylate warning statement on the label, it is not prominent and could easily be overlooked. This could lead to serious medical consequences such as salicylate allergy, salicylate overdosage, and potentially Reye's syndrome. Products containing bismuth subsalicylate could potentially have many drug-to-drug and drug-to-disease interactions, which are described on the product label. Bismuth subsalicylate could interact with anticoagulants, hypoglycemic agents, nonsteroidal anti-inflammatory drugs (NSAIDs), and other anti-inflammatory medications. Medical conditions such as gout, stomach ulcer, kidney disease, and bleeding problems could become more problematic with the use of a salicylate-containing product. Additionally, bismuth subsalicylate can cause darkened or black stools, which could be viewed as evidence of gastrointestinal bleeding.

Here are some measures pharmacists can take in order to avoid confusion:

- Refer to the product by its full product name. For example, say Maalox Total Stomach Relief, Maalox Antacid Barrier, Maalox Regular, or Maalox Max. Do not recommend using the brand/trade name only.
- Provide shelf talkers or some other visual aid to alert consumers to the new bismuth subsalicylate formulation of Maalox. The shelf talker could read: "This [new] product formulation contains a salicylate. Talk to your pharmacist before using."
- Educate patients on the importance of checking the active ingredients in OTC drug products prior to purchase. Encourage patients to read the Drug Facts label for important product information. Encourage patients to ask their pharmacist or healthcare provider when they have questions about differences in formulations.
- Physically separate the different formulations to minimize potential confusion for consumers.
- Advise patients to read and not remove the back panel peel-up label, which contains all the drug facts. It is important because it contains the drug warnings, dosage directions, detailed salicylate warnings, lot number, and expiration date.

If you become aware of medication errors involving Maalox or other products, report them to the FDA MedWatch program online at **www.fda.gov/medwatch.**

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