Maalox brand name extension may cause confusion

We’ve previously alerted readers about over-the-counter (OTC) brand name product line extensions (the same brand name used for products containing different ingredients), which could lead to confusion or patient harm. For example, KAOPECTATE, the familiar anti-diarrheal agent, is now also available as a stool softener containing docusate calcium (March 2005 issue). Similarly, DULCOLAX (bisacodyl), is a stimulant laxative, but is now also available as a stool softener containing docusate sodium (May 2004 issue). Most recently, we were alerted to a new formulation of MAALOX (aluminum-magnesium hydroxide and simethicone) labeled as MAALOX TOTAL STOMACH RELIEF. This new product’s package looks very similar to regular Maalox (see photo), but its ingredients are quite different. Maalox Total Stomach Relief contains only bismuth subsalicylate. A pharmacist told ISMP that she suggested to her grandfather, who was recovering from orthopedic surgery, to take Maalox to control his nausea and upset stomach. Two days later, her grandfather developed black stools, which indicated possible gastrointestinal bleeding. This concerned the pharmacist because her grandfather had also been receiving low molecular weight heparin and aspirin since his surgery. However, the pharmacist’s mother had unknowingly purchased the Maalox Total Stomach Relief product with bismuth subsalicylate. She saw the name Maalox and thought she had the right product. When the pharmacist checked the ingredients, the cause was apparent; bismuth subsalicylate can cause black stools and black tongue.

In reviewing the product labels, it’s easy to see the potential for confusion between the two formulations, but practitioners must be alerted to the formulation change and educate their patients about changes to their regimen in order to prevent under or over dosing.

Safety Briefs

Kaletra - New form, new strength. In late October, Abbott Laboratories introduced a new tablet formulation of KALETRA (lopinavir/ritonavir). The new formulation contains 200 mg lopinavir and 50 mg ritonavir while the capsule formulation contains 133 mg lopinavir and 33.3 mg ritonavir. This change will reduce the number of dosage units required to achieve a complete dose. For example, people taking three Kaletra capsules BID will now only have to take two Kaletra tablets BID. Abbott announced that this new formulation will replace the old capsule formulation by March 2006. In the interim, both new and old formulations are available from wholesalers. Although a letter detailing the changes to healthcare practitioners (http://www.kaletra.com/pdf/HCP_pdf_f.pdf) has been issued, ISMP has been contacted by practitioners who fear that prescribers, pharmacists, nurses, and patients may not realize the full extent of the changes in this new formulation. Those who do not realize that the new dosage form corresponds with a change in formulation of the medication could be at risk for prescribing, dispensing, or administering erroneously high dosages of Kaletra. Abbott hopes that a rapid conversion from the capsules to tablets will help to reduce patient confusion between the two formulations, but practitioners must be alerted to the formulation change and educate their patients about changes to their regimen in order to prevent under or over dosing. Be sure that orders for Kaletra specify the strength of the intended product, not just the number of tablets. If orders lack this information, clarification must be sought prior to dispensing or administering the medication.

Strengthened warnings for Avinza. Ligand Pharmaceutical and FDA recently notified healthcare practitioners regarding revisions to the product labeling for AVINZA (morphine sulfate extended-release capsules). The changes highlight and strengthen warnings that patients should not consume alcohol or...
for mix-ups. As an extension of the well-known Maalox brand, the product is packaged in a white plastic container that is the same size and shape as regular Maalox. “Maalox” is listed prominently on the front label panel of each product. Unfortunately, in the case of Maalox Total Stomach Relief, the bismuth subsalicylate content statement is much less prominent. Additionally, a banner in the upper corner proclaims, “Great new look. Same great Maalox;” however, with totally different ingredients, this is an untruthful and misleading statement because the product only contains bismuth subsalicylate. The new product is also labeled as “Maximum Strength,” which could lead consumers to believe that it just works faster or is stronger than the original product, labeled “Regular Strength.” Warnings pertaining to bismuth subsalicylate are listed on the back label panel, but due to a very small font size, it’s easy to overlook the noteworthy side effects (e.g., black stools and black tongue) and warnings related to use by children or teens with flu symptoms (increased risk of developing Reye’s Syndrome), patients receiving oral anticoagulants, and patients allergic to aspirin. As an OTC “monograph” drug, Maalox does not fall under FDA regulatory control. We have contacted Novartis Consumer Health and they have agreed to look into our labeling concerns.

Please alert all practitioners about this Maalox brand name extension. Many prescribers as well as well as community pharmacists may not be aware of the active ingredient in this new product. It is important that pharmacists are readily available to speak with patients when they select OTC medications. Pharmacies should consider posting alerts for patients on shelves that contain such product line extensions. (e.g., “Although these products have the same brand name, they may contain different ingredients. Please ask the pharmacist for assistance when selecting a Maalox product.”) Likewise, pharmacists and other practitioners should inform patients that many other familiar products may not contain the expected ingredient(s).

Another vaccine mix-up. In our last issue, we reported that multiple contributing factors, including look-alike packaging, led to numerous mix-ups between two meningococcal vaccines: MENOMUNE (meningococcal polysaccharide vaccine groups A, C, Y, and W-135 combined) and MENACTRA (meningococcal [groups A, C, Y, and W-135] polysaccharide diphtheria toxoid conjugate vaccine). A recent report indicates that a similar problem exists between the adult and pediatric strengths of Merck’s hepatitis B vaccines (see photo). A pharmacist noted that a box of adult strength hepatitis B vaccine vials (10 mcg/mL) had been sent to the birthing center instead of the pediatric vaccine (5 mcg/0.5 mL). A nurse discovered the error before administering any doses. After talking to the staff, one of the contributing factors uncovered was look-alike labeling and packaging. The reporter believes the labels do not provide enough visual differentiation despite the difference in border color. We agree that improvements are warranted, and have provided suggested labeling enhancements to the company. Pharmacists have since separated the pediatric and adult strengths in all areas where the product is stocked. An additional option is to affix auxiliary labels to better distinguish the products.
Supervision can be a weak link in error prevention

In order to improve patient safety, ISMP emphasizes that a systems-based approach must be used to analyze mishaps in the medication use system. Some of the more important system-based interventions to help prevent errors include improving the design and workflow of practice sites, using technology and robotics, adding forcing functions to procedures and equipment (e.g., barcode scanners, computer alerts with hard stops), and improving product labels (e.g., circling, highlighting, or using tall man lettering to differentiate product names). But often times, despite these interventions, research shows that unsafe practices continue to exist.

Our attitudes toward work and the management styles that surround us may weaken an organization’s error prevention efforts. Many work environments are punitive, leading practitioners to feel that they can’t make a mistake and if they do, it will be held against them. Paradoxically, these concerns can actually increase anxiety on the job and increase the chances of error. This has been observed among physicians, nurses, and pharmacists in both hospital environments as well as in community pharmacies.¹

A common denominator in overcoming the “I can’t make a mistake” philosophy is building better team relationships and effective supervision. Supervision is not only about providing feedback or overseeing work that is in process or completed. Real supervision includes an examination of the interpersonal processes by which such practices are carried out. Research shows that pharmacists who were most satisfied with their jobs and who were involved in fewer errors had supervisors who fostered appropriate autonomy and were perceived as being democratic, facilitative, and helpful in setting goals. The supervisors were perceived as effective because they demonstrated better leadership and interpersonal skills and encouraged excellence as well as appropriate independence on the job.

On the other hand, professionals who rated their supervisors lower on leadership and interpersonal skills or who perceived them as overly autocratic and punitive, made more mistakes and intercepted fewer errors. In the absence of training and knowledge, people with supervisory responsibilities usually default to management styles that are more controlling rather than interactive. A focus on negative outcomes and the use of autocratic supervision can be a weak link in error prevention.

Safety Briefs (cont’d from previous page)

- Misspelling leads to mix-up. A physician recently prescribed ZEGERID (omeprazole) 40 mg orally each day, but spelled the drug name as it sounded to him. Subsequently, a pharmacist misread the misspelled handwritten order for “Zegrid” as the more familiar drug, ZESTRIL (lisinopril) 40 mg. Zestril is indicated for hypertension, acute myocardial infarction, or heart failure, while Zegerid is used to treat duodenal or gastric ulcers, GERD, erosive esophagitis, or to reduce the risk of upper GI bleeding in critically ill patients. The drugs have overlapping dosage strengths (20 mg, 40 mg) and are administered orally once daily, increasing the risk of mix-ups. Although the pharmacist dispensed Zestril, the error was detected when a nurse called the pharmacist because she was concerned about giving Zestril to her already hypotensive patient. Warn practitioners about the potential for mix-ups with these products, and encourage prescribers to highlight their differences when ordering either medication. Zestril is available in tablets, but Zegerid is supplied in unit-dose packets containing immediate-release omeprazole powder for oral suspension. The generic names for both products are quite dissimilar, so including the generic name and indication on orders for these drugs could help to avoid mix-ups as would counseling patients on all new prescriptions.

Your Reports at Work!

Manufacturer warning: Omacor - Amicar mix-ups. Pharmacies and physicians should have recently received a communication from Reliant Pharmaceuticals warning about the potential for confusing OMACOR (omega-3-acid ethyl esters) prescriptions with AMICAR (aminocaproic acid). Our November 2005 newsletter reported such an incident, and at that time, we had asked the company to take action. We appreciate the timeliness of Reliant’s response and that many of our recommendations were communicated to practitioners. However, we still feel that these two drug names and the shared 1 g oral dosage strengths are far too similar. Thus, we stand by our recommendation that this brand name should be changed. The letter that was faxed to pharmacies in November can be viewed at: http://www.ismp.org/communityarticles/images/reliants.pdf.
**Supervision** (cont’d from previous page)

Suppress error practices creates some of the anxiety, stress, and mental distractions associated with error and job dissatisfaction. See Table 1 below for a list of characteristics (identified by pharmacists) of effective supervisors.

Although people are not necessarily born with great interpersonal and leadership skills, they can learn to supervise appropriately and interact more effectively with their staff. Unfortunately, such training is not pervasive in healthcare and inexperience in how to work with and supervise others often leads to problems. In order to promote effective supervision and error prevention at your site, supervisors should be provided with leadership training that focuses on managing in a positive and participatory manner. In addition, all employees should be taught how to work with supervisors through training related to communication skills, conflict management, and team building. In industries outside of healthcare, such training has resulted in a reduction of safety problems and increased job satisfaction and productivity.

**References:**

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<th>Table 1. Characteristics of Effective Supervisors²</th>
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<tr>
<td>Set clear goals and directions</td>
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<tr>
<td>Establish a climate for excellence and professionalism</td>
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<tr>
<td>Discuss expectations clearly</td>
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<td>Encourage people to enhance their level of performance</td>
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<td>Work with you rather than telling you what to do</td>
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<td>Help set priorities for completing multiple tasks</td>
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<td>Promote critical thinking about how to work effectively</td>
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<td>Motivate and get people excited about their jobs</td>
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<tr>
<td>Use groups to identify and solve problems</td>
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<tr>
<td>Provide sufficient answers to questions</td>
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<tr>
<td>Adjust supervisory styles to accommodate personal differences</td>
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<td>Make people feel involved and important</td>
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Then you to all who attended and/or sponsored this event. Visit [www.ismp.org](http://www.ismp.org) for a list of contributors and information on this year’s winners.

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**The 8th Annual ISMP CHEERS Awards**

It was with great pleasure that we held our 8th Annual ISMP CHEERS Awards Dinner on December 6, 2005 in Las Vegas, NV, to honor some organizations and individuals who have set a standard of excellence in the prevention of medication errors.

Along with those who were recognized in the acute care setting, CHEERS rang out for these Award recipients who effectively brought improved patient safety to the community setting:

- **CLARION**, a student committee of the Center for Health Interprofessional Programs at the University of Minnesota Academic Health Center, was recognized for developing a case competition that brings together healthcare professions from different disciplines—medicine, pharmacy, nursing, public health, and healthcare administration—to solve real problems involving patient safety. The competition was expanded nationally in 2005, when the winning team from the local competition went on to compete with six other schools from across the country.

- **Johns Hopkins Community Physicians** were honored for their dedication to addressing interdisciplinary medication safety issues in the community setting, with a particular focus on non-licensed personnel who administer medications. Other elements of the medication safety campaign include a substantial awards program for staff who recommend safety improvements, an internal newsletter, and an interdisciplinary clinical care committee.

- **Target Corporation** was recognized for its bold step in launching a redesigned pharmacy vial and container, known as the ClearRxSM system, which will hopefully spark similar changes throughout the community pharmacy industry. The system was created by graphic artist Debra Adler after her grandmother mistakenly took her grandfather’s medications. It offers many safety features, including larger, easier-to-read text, placement of the most important information at the top of the label, and attached medication information cards.

Thank you to all who attended and/or sponsored this event. Visit [www.ismp.org](http://www.ismp.org) for a list of contributors and information on this year’s winners.
Special Recognition…

Our 2005 ISMP Medication Safety Alert! Community/Ambulatory Care clinical advisory board

Production of this peer-reviewed newsletter would not be possible without the assistance of a reliable and talented clinical advisory board. As 2005 nears an end, we want to thank each of the following members of the advisory board for their dedication to making this newsletter a valuable medication safety resource for clinicians.

• R. Kenneth Alderfer, RPh, Buckley Pharmacy, King of Prussia, PA
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Happy Holidays…

The staff and trustees at the Institute for Safe Medication Practices wish you joy, health, and happiness this holiday season!

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