

NONPRESCRIPTION MEDICINES DIGEST



March 22, 2004

Welcome to the March NMA Newsletter. This month we report some suggestions for pharmacists trying to deal with the FDA ban on ephedra-containing products, the risk for adverse ocular effects from a lice shampoo, and information for pharmacists concerning aspirin and cardiovascular disease prevention guidelines for women. Past articles and updates can be found at <http://www.nmafaculty.org>. Coming up in April will be some additions to the Resource links on thermotherapy, and several teaching tools for faculty.

Faculty Resources

Share ideas with colleagues on the faculty-only area of the website, which is designed to facilitate the exchange of course materials such as syllabi, cases, and exam questions. Become part of the online academy by [registering](#) to join this free service, and help foster the exchange of ideas.

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Update on Ephedra: What should pharmacists do now?

Kristin Casper, Pharm.D.

Most healthcare professionals have now heard about the recent FDA-issued regulation prohibiting the sale of dietary supplements containing ephedrine alkaloids (ephedra). FDA issued the final ruling in February 2004, concluding that supplements containing ephedrine alkaloids present an "unreasonable risk" to



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consumers. The ruling will take effect in 60 days, by which time all ephedra-containing products should be removed from pharmacy shelves. Products that are affected by this ruling include all dietary supplements that contain a source of ephedrine alkaloids with ingredients such as ephedra, Ma huang, and other less commonly known names such as country mallow, heartleaf, *Sida cordifolia*, and pinellia. The *Pharmacist's Letter* has created a list of ephedra-containing products to make the job of product identification and removal a bit easier. Pharmacists should also warn their patients that use of ephedra-containing products is not recommended and even products that are purchased from other countries such as Canada or on the Internet, still present similar risks of increased blood pressure, heart attack and stroke, regardless of the companies' claims. Pharmacists should also let patients know that companies may be looking for replacement products such as bitter orange (*Citrus aurantium*) and herbal products that may contain large amounts of caffeine such as guarana, black tea, green tea, and cola/kola nut. For more information about FDA's ruling on ephedra products, visit www.fda.gov/oc/initiatives/ephedra/february2004/finalsummary.html or www.pharmacistsletter.com.

Adverse Ocular Effects from Over-the-Counter Lice Shampoo

Fraunfelder FW, Fraunfelder FT, Goetsch RA
Archives of Ophthalmology 2003;121(12):1790-1

Pharmacists are often asked for advice when selecting a product to treat head lice. This case report describes a product marketed as *Lice R Gone*® (Safe Solutions, Inc.; <http://www.licergone.com>) resulting in 15 reported cases of severe ocular irritation. *Lice R Gone*® is a shampoo that is marketed as a safer alternative when compared to conventional head lice treatments (like Nix® or Rid®) and claims to contain no pesticides, toxins, or chemicals. However, the authors note that 15 patients, who reported using the shampoo according to the manufacturer's instructions, reported immediate adverse ocular reactions including seven cases of corneal abrasion and seven separate cases of severe eye irritation. Among the 15 patients, 6 also reported severe ocular pain, 6 experienced abnormal vision, and 1 reported blindness (with no follow-up data to determine symptom resolution). The authors indicate that eye irritation may occur with topical solutions that are used in close proximity to the eyes (such as shampoos for the head), but the usual reaction is generally transient eye irritation or redness. The occurrence of corneal abrasion was of particular concern because this condition may be associated with severe ocular pain and may increase the risk of bacterial infection. Pharmacists are encouraged to counsel patients that if a product causes an adverse ocular reaction, the patient should flush the eye with large amounts of water and follow up with an ophthalmologist if the symptoms do not subside after 24 hours. This information is not always included in the package insert, so pharmacists can serve as a valuable source of information. Cases of ocular reactions associated with any medication can be reported online to <http://www.eyedrugregistry.com>.

Preventing Cardiovascular Disease in Women: How New Guidelines May Impact Pharmacists' Recommendations for Aspirin Therapy

AHA Evidence-Based Guidelines for Cardiovascular Disease Prevention in Women

Circulation 2004;109:672-693

As pharmacists continue to expand their roles as valuable members of the healthcare team, they may begin to take more responsibility for steering patients in the right direction when it comes to disease prevention. The recent evidence-based guidelines for the prevention of cardiovascular disease in women, published by the American Heart Association in February 2004, will serve as a valuable resource to help pharmacists make recommendations for all women at risk for cardiovascular disease. Cardiovascular disease (CVD) still remains the leading cause of death among women in the United States. The 2003 heart disease statistics from AHA also indicate that women often die suddenly from coronary heart disease (which accounts for the majority of CVD deaths) and nearly two-thirds of these women do not experience prior symptoms. Therefore, prevention is the key. Of the nonprescription recommendations that could be considered with CVD prevention, helping women make informed decisions about using aspirin therapy to prevent CVD may be a logical role for the pharmacist. The expert panelists whom collaborated to create the guidelines indicated that aspirin therapy at a dose of 75-162 mg per day should be used for preventing CVD in women who are categorized as "high risk" based on the Framingham Global Risk available at <http://www.nhlbi.nih.gov/guidelines/cholesterol/index.htm>. Women who are at "intermediate risk" should consider aspirin therapy as long as their blood pressure is under control and the benefit of aspirin outweighs the potential for gastrointestinal side effects. As for women who are considered "lower risk", aspirin therapy is not currently recommended. With these new guidelines, which also include classifications, levels of evidence, and generalizability data for each of the recommendations, pharmacists can help women determine their overall risk for CVD and decide if preventative aspirin therapy is an appropriate choice. More information about recommendations for aspirin therapy and overall CVD prevention can be found in the guidelines at <http://www.circulationaha.org>.