

AU InforMed

Volume 5 Number 5 (Issue 140)

Wednesday, Feb 14, 2007



Key Inforbits

- Orlistat now over-the-counter
- Several important MedWatch notices
- New guidelines issued for DVT
- Health literacy
- More evidence of “No Free Lunch”
- Affairs of the heart

NEW DRUGS, and other related stuff ...

Rx to OTC Switch ... The FDA today approved **orlistat capsules** (Xenical[®] by Roche Labs) as an over-the-counter (OTC) weight loss aid for overweight adults. Orlistat was initially approved in 1999 as a prescription drug to treat obesity, and remains a prescription drug for obesity at a higher dose than the OTC version. OTC orlistat will be manufactured by GlaxoSmithKline under the name **Alli™** and is indicated for use in adults ages 18 years and older along with a reduced-calorie, low-fat diet, and exercise program. Orlistat helps produce weight loss by decreasing the intestinal absorption of fat. The 60 mg capsule can be taken up to three times a day with each fat-containing meal. Because of the possible loss of certain nutrients, it is recommended that people using orlistat should also take a multivitamin at bedtime. The most common side effect of the product is a change in bowel habits, which may include loose stools. Eating a low fat diet will reduce the likelihood of this side effect.

FDA approves orlistat for over-the-counter use. *FDA News*. 2007 Feb 7; P07-15.

<http://www.fda.gov/bbs/topics/NEWS/2007/NEW01557.html>

MedWatch ... The FDA informed consumers and healthcare professionals of the potential **hazards of using skin numbing products** containing **topical anesthetic** drugs such as lidocaine, tetracaine, benzocaine, and prilocaine in a cream, ointment, or gel. Numbing products are widely used to numb the skin for medical and cosmetic procedures, and to relieve pain, burning and itching due to a variety of medical conditions. FDA has approved many of these products for these uses. Some of these products must be prescribed by a doctor, while others may be purchased without a prescription. FDA is aware that use of these products before a cosmetic procedure may not be supervised by trained health professionals. Without this supervision, a patient may apply large amounts of the numbing product to their skin, which can cause life-threatening side effects and death. If a skin numbing product is prescribed or recommended for a procedure, consumers should do the following:

- use a topical anesthetic approved by the FDA.
- use a topical anesthetic that contains the lowest amount of anesthetic drugs possible that will relieve pain.
- ask for instructions from your doctor on how to safely use the topical anesthetic.

Read the complete MedWatch 2007 Safety summary, including the link to the FDA's Public Health Advisory regarding this issue at:

<http://www.fda.gov/medwatch/safety/2007/safety07.htm#Anesthetics>

MedWatch ... Baxter and FDA notified healthcare professionals of the potential for **life threatening medication errors involving two Heparin products**, Heparin Sodium Injection 10,000 units/mL and HEP-LOCK U/P 10 units/mL. Baxter is aware of fatal medication errors that have occurred when two Heparin products with shades of blue labeling were mistaken for each other. Three infant deaths resulted when the higher dosage Heparin Sodium Injection 10,000 units/mL was inadvertently administered instead of the lower dosage of HEP-LOCK U/P 10 units/mL. The currently marketed 1 mL vials of both Heparin products use blue as the prominent background color on their labels.

Read the complete MedWatch 2007 Safety summary, including a link to the Baxter Dear Healthcare Provider letter, at:

<http://www.fda.gov/medwatch/safety/2007/safety07.htm#Heparin>

MedWatch ... FDA and Sanofi-Aventis notified healthcare professionals of revisions to the prescribing information, including a **BOXED WARNING** and a new Patient Medication Guide, for the antibiotic **Ketek (telithromycin)**. Two of the three previously approved indications, acute bacterial sinusitis and acute bacterial exacerbations of chronic bronchitis, were removed from the prescribing information because the balance of benefits and risks no longer support approval of the drug for these indications. Ketek will remain on the market for the treatment of community acquired pneumonia of mild to moderate severity. In addition, warnings were strengthened for hepatotoxicity (liver injury), loss of consciousness, and visual disturbances. The BOXED WARNING states that Ketek is contraindicated in patients with myasthenia gravis. The Patient Medication Guide, which must be distributed to all patients, informs them about the risks of the drug and how to use it safely.

Read the complete MedWatch 2007 Safety summary, including links to the FDA Press Release and Drug Information Page and the Manufacturer's revised prescribing information and Medication Guide for Ketek regarding this issue at:

<http://www.fda.gov/medwatch/safety/2007/safety07.htm#Ketek>

MedWatch ... The FDA issued a Public Health Notification to inform health care providers and consumers about 28 post-marketing reports of **intussusception following administration of Rotavirus, Live, Oral, Pentavalent vaccine (RotaTeq)**. Intussusception is a serious and potentially life-threatening condition that occurs when the intestine gets blocked or twisted. Because vaccine adverse events are not always reported to FDA, there may be additional cases of intussusception following vaccination of which we are unaware. This information is important in helping FDA and CDC assess whether RotaTeq may be associated with an increased risk of intussusception and, if so, to what degree. Healthcare professionals and others are encouraged to report any cases of intussusception or other serious events that may be associated with the use of RotaTeq to the Vaccine Adverse Event Reporting System (VAERS). Parents should contact their child's doctor immediately if the child has stomach pain, vomiting, diarrhea, blood in their stool or change in their bowel movements, as these may be signs of intussusception.

Read the complete MedWatch 2007 Safety summary, including links to the Notification, Label and Patient Product Information, at:

<http://www.fda.gov/medwatch/safety/2007/safety07.htm#RotaTeq>

FROM THE MEDICAL LITERATURE ...

Natural products gone bad ... Three case reports of apparent natural product-induced adverse effects. Three boys aged 4 to 10 years experienced gynecomastia after using personal-care products (eg, soaps, shampoos). After extensive questionings, these products appeared to be the culprits; the gynecomastia resolved after withdrawal of the products. See also the related article below.

Henley DV, Lipson N, Korach KS, Bloch CA. Prepubertal gynecomastia linked to lavender and tea tree oils. *N Engl J Med*. 2007 Feb 1;356(5):479-85.



Guidelines for DVT ... New clinical practice guidelines for the management of venous thromboembolism have been issued by the American College of Physicians and the American Academy of Family Physicians. In addition to the Guidelines, also published is the systematic review used to create the guideline and a 'Summary for Patients' that may help educate patients about the guidelines and their use.



Pulmonary valve

Snow V, Qaseem A, Barry P, Hornbake ER, Rodnick JE, Tobolic T, et al. Management of venous thromboembolism: A clinical practice guideline from the American College of Physicians and the American Academy of Family Physicians. *Ann Intern Med*. 2007 Feb 6;146(3):204-210.

Segal JB, Streiff MB, Hoffman LV, Thornton K, Bass EB. Management of venous thromboembolism: A systematic review for a practice guideline. *Ann Intern Med*. 2007 Feb 6;146(3):211-222.

Treatment of venous thromboembolism: Recommendations from the American College of Physicians and the American Academy of Family Physicians. *Ann Intern Med*. 2007 Feb 6;146(3):I-43.

Reviews of Note ...

- Laine C, Goldmann D, eds. In the clinic: Smoking cessation. *Ann Intern Med*. 2007 Feb 6;146(3):ITC2-1 – ITC2-15.
- Abramowicz M, ed. Drugs for cognitive loss and dementia. *Treatment Guidelines Med Lett*. 2007 Feb;5(54):9-14.

FROM THE LAY LITERATURE about medicine ...

Health Literacy ... The focus is the patient-physician interaction while in the examining room, but it easily carries to the prescription counter and counseling booth. To be effective, communication with the patient must be on their level, and it's up to you to determine such. It is emphasized how easy it is for patients to misinterpret seemingly straightforward instructions; assuring baseline understandings, ask "what questions do you have;" have the patient repeat the instructions; and if it involves a skill (eg, injection, inhaler) have them demonstrate for you.



Brody JE. The importance of knowing what the doctor is talking about. *New York Times*. 2007 Jan 30.

http://www.nytimes.com/2007/01/30/health/30brody.html?_r=1&ref=health&oref=slogin

No free lunch?? ... Based on an article last year in *JAMA* (see *AU InforMed* 2006 Feb 1;4(4):13-16) in which a coalition of physicians proposed that academic medical centers take the lead in refusing pharmaceutical company largess in the form of samples, free lunches, etc, a group dubbed the Prescription Project is attempting to spread those restrictions. The theoretical advantages are saving the pharmaceutical industry money in their advertising budget which should lower prescription prices (but where would they



really spend it?) and physicians would be less influenced (ever so subtly) to prescribe expensive new drugs. Sounds good, but ...

Saul S. Doctors and drug makers: A move to end cozy ties. *New York Times*. 2007 Feb 12.

http://www.nytimes.com/2007/02/12/business/12drug.html?_r=1&ref=health&oref=slogin

AUBURN HSOP FACULTY in the literature ...

- **Braxton Lloyd K**, Thrower MR, Walters NB, Krueger KP, **Stamm PL**, **Evans RL**. Implementation of a weight management pharmaceutical care service. *Ann Pharmacother*. 2007 Feb;41:DOI 10.1345/aph.1E466.
- Bell EC, **Ravis WR**, **Braxton Lloyd K**, Stokes TJ. Effects of St. John's Wort supplementation on ibuprofen pharmacokinetics. *Ann Pharmacother*. 2007 Feb;41:DOI 10.1345/aph.1H602.

NEW RESOURCES in the DILRC ...

- Kahn CM, ed. *The Merck Veterinary Manual*. 9th ed. Whitehouse Station, NJ: Merck & Co, 2005.
- Beardsley RS, Kimberlin CK, Tindall WN. *Communication Skills in Pharmacy Practice*. 5th ed. Baltimore: Lippincott Williams & Wilkins/Wolters Kluwer Health, 2007.
- *Directory of Residencies, Fellowships, and Graduate Programs 2007*. Kansas City, MO: American College of Clinical Pharmacy, 2007.



The last "dose" ...



The Heart



[The heart] moves of itself and does not stop unless forever.

-- Leonardo da Vinci, 1510, *Notebooks*



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