

AU InforMed

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Key Inforbits

- New format for package inserts from the FDA
- Xenical[®] going OTC???
- Liver warning for Ketek[®]!
- Functional foods seminar coming up
- Using bad words on your resume ...
- **100th** issue of *AU InforMed*

NEW DRUGS, and other related stuff ...

FDA announces new package inserts ... The FDA today announced a major revision to the format of the package insert. The newly designed package insert will provide the most up-to-date information in an easy-to-read format that draws attention to the most important pieces of drug information. The new format will also be more compatible with electronic prescribing tools and other electronic information resources. Revised for the first time in more than 25 years, the new format requires that the prescription information for new and recently approved products meet specific graphical requirements and includes the reorganization of critical information. Some of the most significant changes include:

- Graphical requirements
- Reorganization of critical information
- A new section, *Highlights*, to provide immediate access to the most important prescribing information. This will be at the top of the page.
- A *Table of Contents* for easy reference to detailed safety and efficacy information.
- The date of initial product approval.
- A toll-free number and Internet reporting information for suspected adverse events.
- New patient counseling information

In addition, as information is updated it will be used to provide medication information for *DailyMed* -- a new interagency online health information clearinghouse that will provide the most up-to-date medication information free to consumers, healthcare professionals and healthcare information providers. This information can be accessed through the National Library of Medicine at <http://dailymed.nlm.nih.gov>.

FDA. FDA announces new prescription drug information format to improve patient safety. *FDA News* 2006 Jan 18;P06-08.

<http://www.fda.gov/bbs/topics/NEWS/2005/NEW01272.html> (FDA News site)

<http://www.fda.gov/cder/regulatory/physLabel/default.htm> (Announcement and other documents)

Coming soon? ... An FDA advisory panel, in an 11-3 vote, recommended to the Commissioner that orlistat (Xenical[®] by Roche) be approved as a nonprescription (OTC) product. If approved, it will be marketed as *Alli*, by GlaxoSmithKline; it will be the first drug of this kind to be marketed OTC. While the advisory panel was overwhelmingly positive, there are its detractors, citing such concerns as potential side effects, abuse by those seeking fast weight loss (eg, teenagers) and yet another excuse not to diet and exercise. Stay tuned.

Associated Press. Fat-blocking pill wins FDA endorsement. *New York Times.com* 2006 Jan 24.

<http://www.nytimes.com/aponline/health/AP-Diet-Pill.html>

New Labeling ... The FDA approved updated labeling on January 19, 2006 for two topical eczema drugs, Elidel[®] Cream (pimecrolimus) and Protopic[®] Ointment (tacrolimus). The labeling will be updated with a boxed warning about a possible risk of cancer and a Medication Guide (FDA-approved patient labeling) will be distributed. The new labeling also clarifies that these drugs are recommended as second-line treatments; therefore other prescription topical medicines should be tried first. Use in children under 2 years of age is not recommended.

<http://www.fda.gov/cder/drug/infopage/elidel/default.htm>

<http://www.fda.gov/cder/drug/infopage/protopic/default.htm>

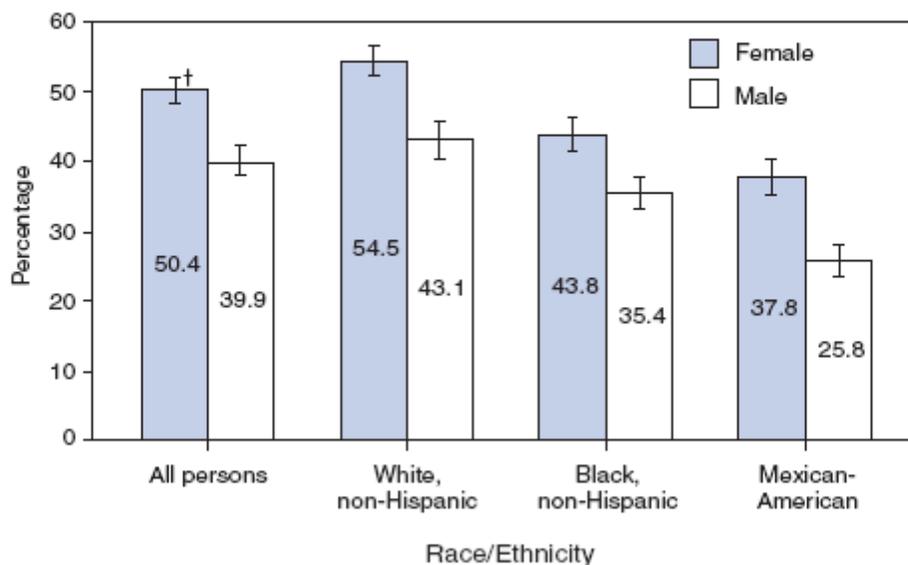
MedWatch ... The *Annals of Internal Medicine* published (January 20, 2006 online; March 21, 2006 in print) an article reporting three patients who experienced serious liver toxicity following administration of Ketek (telithromycin). These cases were also reported to FDA MedWatch. The FDA is evaluating the issue of liver problems in association with use of telithromycin to determine if labeling changes or other actions are necessary. In addition, the FDA is continuing to work to better understand the frequency of liver-related adverse events reported for approved antibiotics, including telithromycin.

Read the complete MedWatch 2006 Safety summary, including links to the Public Health Advisory and Q&A's, at:

<http://www.fda.gov/medwatch/safety/2006/safety06.htm#Ketek>

FROM THE MEDICAL LITERATURE ...

Percentage* of Persons Reporting Use of At Least One Prescription Drug During the Preceding Month, by Sex and Race/Ethnicity — United States, 1999–2002



CDC. QuickStats: Percentage of Persons Reporting Use of At Least One Prescription Drug During the Preceding Month, by Sex and Race/Ethnicity-United States, 1999-2002. *MMWR*. 2006 Jan 13;55(01):15.
<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5501a6.htm>

Reviews of Note ...

- Yager JD, Davidson NE. Estrogen carcinogenesis in breast cancer. *N Engl J Med*. 2006 Jan 19;354(3):270-82.
- Buettner C, Yeh GY, Phillips RS, Mittleman MA, Kaptchuk TJ. Systematic review of the effects of ginseng on cardiovascular risk factors. *Ann Pharmacother*. 2006 Jan;39(1):83-95.
- Triplitt C, Chiquette E. Exenatide: From the Gila Monster to the pharmacy. *J Am Pharm Assoc*. 2006 Jan/Feb;46(1):44-55.
- Berger JS, Roncaglioni MC, Avanzini F, Pangrazzi I, Tognoni G, Brown DL. Aspirin for the primary prevention of cardiovascular events in women and men: A sex-specific meta-analysis of randomized controlled trials. *JAMA*. 2006 Jan 18;295(3):306-313.

FROM THE LAY LITERATURE about medicine ...



Meth toll continues to rise ... Two surveys released recently, conducted by the National Association of Counties, present data that the methamphetamine problem continues to increase. It is taking a serious toll on county health facilities, particularly rural and in the Midwest, though certainly not limited to there. Methamphetamine is often cited by hospitals and emergency rooms as their number one drug problem. In addition to its addictive nature, these cases are often more expensive due to extra staff needed, longer treatment programs required and the patient are commonly uninsured. Peripherally, children living in the homes of abusers are often involved, as well as others (eg, crime targets), as victims of the meth-induced aggression.

Zernike K. Hospitals say meth cases are rising, and hurt care. *New York Times.com* 2006 Jan 18.

<http://www.nytimes.com/2006/01/18/national/18drug.html>

Leinwand D. Meth cases put strain on ERs. *USA Today* 2006 Jan 17.

http://www.usatoday.com/news/nation/2006-01-17-meth-hospitals_x.htm



Pharmaceutical Calculations ... perhaps an addition to the curriculum?!? A recent article tested the costs of drugs, based on acquisition from Canada compared to the least expensive Medicare Part D plan, using 90-day mail order prices. Their conclusion, after comparing five different combinations ranging from one drug to six drugs is that only one time did the Canadian source come up cheaper (the single drug). The other four combinations were cheaper in the Medicare Part D comparison by a significant percent. *Submitted by Dr. Robert E. Smith Barry P.* The new math: Can a Medicare Rx plan cost less than buying drugs from Canada? *AARP Bull* 2006 Jan;47(1):22.

Update ...



Functional Foods: The New Medicine ... Take Control of Your Health by the Foods You Eat. This is the topic of the 2006 Urban Rural Interface Conference, sponsored by the Alabama Cooperative Extension Service and Auburn University, Montgomery. It is being held

this year in Huntsville, AL on April 20, 2006. The discussion centers around the health benefits of fruits, vegetables and mushrooms, beyond the nutritional value. With information on nutrition and exercise appearing on a seemingly weekly basis, this may be a good opportunity. For further information go to:

<http://webspaace.aamu.edu/ag/sps/FunctionalFoodsConference/FunctionalFoods.html>

TIMELY TOP JOB TIP ...



Bad words for résumé ... For those looking, and soon to be looking, for a job, here are a few suggestions from some experts. Wording on a résumé can be critical, and most importantly, whatever you write down, be prepared to back up. A list of 25 words is offered to carefully consider before using on your résumé, particularly if you cannot cite specific (and impressive) examples. Some of the words include: Aggressive, detail-oriented, experienced, motivated, successful, and team player. For more information, go to the web site below.

Morsch L. 25 words that hurt your resume: Words don't tell potential employers as much as deeds. *CNN.com* 2006 Jan 20.

<http://www.cnn.com/2006/US/Careers/01/20/cb.words.hurt.resume/index.html>

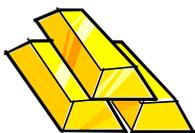


The last "dose" ...

Did you know?

The word "diet" is derived from the Greek *diáita*, "a way of living or a mode of life." It originally referred more to general hygiene. It eventually became associated with eating, BUT, so as to be conducive to good health.

Haubrich WS. *Medical Meanings: A Glossary of Word Origins*. 2nd ed. Philadelphia: American College of Physicians, 2004, p. 67.



This marks the 100th issue of *AU InforMed*. Congratulations to the entire editorial staff!

An electronic bulletin of drug and health-related news highlights, a service of ...

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