

AU InforMed

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Friday, September 30, 2005



Key Inforbits

- Lots of MedWatches
- Flu vaccine priorities
- Two reviews on the Avian Flu and drugs for it
- Local music star 
- Walk to School Week
- National Pharmacy Week 10/23-29

NEW DRUGS, and other related stuff ...

New Generic ... AZT ... Zidovudine (Retrovir[®] by GlaxoSmithKline first approved in 1987) has been approved for generic availability and several companies will pursue manufacturing and marketing. They are Ranbaxy Laboratories of India, Aurobindo Pharma LTD of India, and Roxane Laboratories of Columbus, OH.

FDA. FDA approves first pediatric generic AIDS drug for U.S. marketing. *FDA News* Sep 19; P05-61.

<http://www.fda.gov/bbs/topics/NEWS/2005/NEW01232.html>

New Indication ... The FDA has approved additional indications for **atorvastatin calcium (Lipitor[®] by Pfizer)** to reduce the risk of stroke and heart attack in people with type 2 diabetes without evidence of heart disease but with other risk factors, on September 27, 2005.

Atorvastatin also received approval to reduce the risk of stroke in people without evidence of heart disease but with multiple risk factors other than diabetes. Common risk factors for heart disease include high cholesterol, high blood pressure, family history, age over 55, smoking, diabetes and obesity. The FDA's decision was based on the findings of the Collaborative Atorvastatin Diabetes Study (CARDS), a landmark trial of more than 2,800 patients with type 2 diabetes, near normal cholesterol, and at least one other risk factor, such as high blood pressure or smoking. It showed that patients on atorvastatin experienced nearly 50% fewer strokes compared to placebo. The CARDS trial was stopped nearly two years earlier than planned by the study's Steering Committee because of the strong benefits among patients who took the drug.

http://www.pfizer.com/pfizer/are/news_releases/2005pr/mn_2005_0927.jsp (Pfizer press release)

MedWatch ... Med Errors ... AstraZeneca and FDA notified healthcare professionals of reports of medication dispensing or prescribing errors between Toprol-XL[®] (metoprolol succinate) extended release tablets, indicated for hypertension, angina pectoris, and heart failure, and Topamax[®] (topiramate by Ortho-McNeil Neurologics), indicated for epilepsy and migraine prophylaxis. There have also been reports of medication errors involving confusion between Toprol-XL[®] and Tegretol[®] or Tegretol-XR[®] (carbamazepine), products of Novartis Pharmaceuticals, indicated for complex partial seizures, generalized tonic-clonic seizures, and trigeminal neuralgia. These reports include instances where Toprol-XL[®] was incorrectly administered to patients instead of Topamax[®], Tegretol[®], or Tegretol-XR[®], and vice versa, some of them leading to adverse events. Read the complete MedWatch 2005 Safety summary, including links to the Dear Healthcare Professional and Dear Pharmacist letters, at:

<http://www.fda.gov/medwatch/safety/2005/safety05.htm#Toprol>

MedWatch ...GlaxoSmithKline (GSK) and FDA announced changes to the Pregnancy/Precautions section of the Prescribing Information for Paxil[®] and Paxil CR[®] to describe the results of a GSK retrospective epidemiologic study of major congenital malformations in infants born to women taking antidepressants during the first trimester of pregnancy. This study suggested an increase in the risk of overall **major congenital malformations for paroxetine** as compared to other antidepressants [OR 2.2; 95% CI, 1.34-3.63]. Healthcare professionals are advised to carefully weigh the potential risks and benefits of using paroxetine therapy in women during pregnancy and to discuss these findings as well as treatment alternatives with their patients.

Read the complete MedWatch 2005 Safety summary, including links to the Dear Healthcare Professional Letter and revised labeling, at:

<http://www.fda.gov/medwatch/safety/2005/safety05.htm#Paxil2>

MedWatch ... American Pharmaceutical Partners, Inc. and FDA announced a nationwide recall of **Fluorouracil Injection 50 mg/mL (500 mg/10 mL Single Dose Vial)** because of the potential for invisible glass particles containing silica and aluminum in vials of the product. The company states that only Product code 101710 is susceptible to this type of glass breakdown.

Read the complete MedWatch 2005 Safety summary, including links to FDA and sponsor's recall notice and sponsor's Dear Healthcare Professional

Letter:<http://www.fda.gov/medwatch/safety/2005/safety05.htm#Fluorouracil>

MedWatch ... The FDA directed Eli Lilly and Company, the manufacturer of **Strattera[®] (atomoxetine)**, to revise the prescribing information to include a boxed warning and additional warnings concerning an increased risk of suicidal thinking in children and adolescents being treated with this medication. FDA also informed Lilly that a Patient Medication Guide (MedGuide) should be provided to patients when Strattera[®] is dispensed. Further, pediatric patients being treated with Strattera[®] should be closely observed for clinical worsening, as well as agitation, irritability, suicidal thinking or behaviors, and unusual changes in behavior, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases.

Read the complete MedWatch 2005 Safety Summary, including a link to the FDA Public Health Advisory and Press Release, FDA Drug Information Page, Healthcare Professional Information Sheet, and FDA Patient Information Sheet:

<http://www.fda.gov/medwatch/safety/2005/safety05.htm#Strattera>

FROM THE MEDICAL LITERATURE ...



Older is better ... you don't hear that very often! In a study of 1493 schizophrenic patients, randomized to receive olanzapine (Zyprexa[®]), perphenazine (eg, Trilafon[®]), quetiapine (Seroquel[®]), risperidone (Risperdal[®]), or ziprasidone (Geodon[®]), all of the drugs performed approximately the same for efficacy and tolerability (that is to say, not very well). In the study, 62% to 82% of patients discontinued the drugs due to various problems. The big news (particularly as reported in the press) is that an old-timer, perphenazine, performed equally as well (or bad) as the rest of the "new and improved" agents.

Lieberman JA, Stroup TS, McEvoy JP, Swartz MS, Rosenheck RA, Perkins DO, et al. Effectiveness of antipsychotic drugs in patients with chronic schizophrenia. *N Engl J Med.* 2005 Sep 22;353(12):1209-23.



Flu Vaccine Priority ... To have a better idea of the demand vs. existing supplies, the CDC recommends the following groups receiving priority in receiving the trivalent influenza vaccine:

- persons aged ≥ 65 years with comorbid conditions
- residents of long-term-care facilities
- persons aged 2-64 years with comorbid conditions
- persons aged ≥ 65 years without comorbid conditions
- children aged 6-23 months
- pregnant women
- health-care personnel who provide direct patient care
- household contacts and out-of-home caregivers of children aged < 6 months

Update: Influenza Activity-United States and Worldwide, May 22-September 3, 2005, and 2005-06 Season Vaccination Recommendations *MMWR* 2005 Sep 16;54(36):899-902.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5436a3.htm>

Reviews of Note ...

- The Lewis Group. Medication therapy management services: A critical review. *J Am Pharm Assoc.* 2005 Sept/Oct;45(5):580-87.
- Ashen MD, Blumenthal RS. Low HDL cholesterol levels. *N Engl J Med.* 2005 Sep 22;353(12):1252-60.
- Kaplan MM, Gershwin ME. Primary biliary cirrhosis. *N Engl J Med.* 2005 Sep 22;353(12):1261-73.
- Moscona A. Neuraminidase inhibitors for influenza. *N Engl J Med.* 2005 Sep 29;353(13):1363-73.
- The Writing Committee of the World Health Organization Consultation on Human Influenza A/H5. Avian influenza (H5N1) infections in humans. *N Engl J Med.* 2005 Sep 29;353(13):1374-85. [Free full text available at <http://content.nejm.org/>]

Update ...

Li E. Oncology pharmacy practice residency programs. *Am J Health-Syst Pharm* 2005 Oct 1;62:1980-81.

AUBURN HSOP FACULTY/STAFF/STUDENTS in the literature ...

-  Notable: **Jane Drake.** *Opelika-Auburn News* 2005 Sep 16;101(259):1. A graphic artist in the HSOP OIT Dept, Ms. Drake is launching a music CD “Brand New Woman” featuring original compositions and jazz standards.
- Chandler H, Thrower MR, Olin BR. New antibiotic: telithromycin (Ketek). *Alabama Pharmacy.* 2005 Sum;38:23-25.
- Garrett M, Olin BR, Thrower MR. Ephedra-containing products vs. ephedra-free products. *Alabama Pharmacy.* 2005 Sum;38:33-35.
- Hagler L. Avian flu pandemic. *Alabama Pharmacy.* 2005 Sum;38:30-32.

NEW RESOURCES in the DILRC ...

- Anderson S, ed. *Making Medicines: A Brief History of Pharmacy and Pharmaceuticals*. London: The Pharmaceutical Press, 2005.
- Taketomo CK, Hodding JH, Kraus DM. Lexi-Comp's *Pediatric Dosage Handbook*. 12th ed. Hudson, OH: Lexi-Comp, 2005.
- Wells BG, DiPiro JT, Schwinghammer TL, Hamilton CW. *Pharmacotherapy Handbook*. 6th ed. New York: McGraw-Hill, 2006.

TIMELY TOP TECH TIP ...

 **Reminder:** For those who like reference material on your PDA, don't forget that two of our Online Resources, *Micromedex* (mobileMICROMEDEX) and *Clinical Pharmacology* (Clinical Pharmacology OnHand), offer a free download of their PDA database, as part of our subscription.

The last "dose" ...



International Walk to School Week - October 3-7, 2005



This designation enables children, parents, teachers, and community leaders to be part of a global event celebrating the benefits of walking and the need to create communities that are safe for pedestrians. In 2004, approximately 3 million walkers in 36 countries observed the weeklong event by walking to school. The CDC supports International Walk to School Week and walking and bicycling to school year-round through Safe Routes to School (SR2S) programs. *KidsWalk-to-School* is a community-based SR2S program that encourages walking and bicycling to school. In 2005, Congress passed a transportation bill that includes \$612 million in funds for SR2S programs to enhance safety for children walking or bicycling to school. State departments of transportation will administer the program, and communities will be able to use the funds to make infrastructure improvements near schools (e.g., removing road hazards, slowing traffic, building sidewalks, and creating walking trails) and enhance safety through enforcement and education programs.

KidsWalk-to-School information is available at

<http://www.cdc.gov/nccdphp/dnpa/kidswalk/index.htm>. Information on International Walk to School Week is available at <http://www.walktoschool-usa.org> and <http://www.iwalktoschool.org>.

Information on SR2S is available at <http://www.saferoutesinfo.org>.

Morbidity and Mortality Weekly Report (MMWR) 2005 Sep 30; 54(38):949.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5438a1.htm>



National Pharmacy Week, October 23-29, 2005



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

Auburn University, Harrison School of Pharmacy, Drug Information Center

- Phone 334-844-4400 • Fax 334-844-8366 • <http://www.pharmacy.auburn.edu/dilrc/dilrc.htm>
- Bernie R. Olin, Pharm.D., Director*