

AU InforMed

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Key Inforbits

- TWO new drugs approved
- New shingles vaccine recommendation
- Disease risk calculator
- Do you believe all you read ...
- Disease creation
- Free newsletter available

NEW DRUGS, and other related stuff ...

New Drug ... Kunecatechins (Veregen™ by Medigene) was approved by the FDA on October 31, 2006. This is a topical ointment for the treatment of external and perianal genital warts. Medigene is a German biotech company and its U.S. partner for this product will be Bradley Pharmaceuticals. Kunecatechins is an extract of green tea leaves. The product is expected on the U.S. market in the second half of 2007. It is on the German market as Polyphenon® E Ointment

<http://www.medigene.de/englisch/pressemitteilungen.php?ID=2158>

New Drug ... The FDA, October 25, 2006, approved **telbivudine (Tyzeka™** by Novartis Pharma Stein AG) for the treatment of adults with **chronic hepatitis B (HBV)**, a serious viral infection that attacks the liver and can cause lifelong infection, scarring of the liver (cirrhosis), and eventually liver cancer, liver failure, and death. "In a typical year, an estimated 70,000 Americans become infected with chronic HBV, and some 5,000 of them will die of the complications caused by the disease," said Dr. Steven Galson, Director of the Center for Drug Evaluation and Research. Telbivudine is not a cure for hepatitis B, and long-term treatment benefits of this drug are not known. Use of telbivudine has not been shown to reduce the risk of transmission of HBV to others through sexual contact or blood contamination. Patients should only stop telbivudine after a careful discussion with their doctor. As has happened with other forms of treatment for hepatitis B, some patients who discontinued telbivudine experienced a sudden and severe worsening of their hepatitis B.

FDA approves new treatment for chronic hepatitis B in adults. *FDA News*. 2006 Oct 25;P06-175.

<http://www.fda.gov/bbs/topics/NEWS/2006/NEW01498.html>

<http://www.novartis.com/products/en/index.shtml> [Novartis Media Relations → Media Releases]

New Indications ... Gleevec® (imatinib) has gained approval for five rare, life-threatening diseases. The uses include treatment of the solid tumor cancer, dermatofibrosarcoma protuberans, and four hematological disorders, Philadelphia chromosome-positive acute lymphoblastic leukemia, hypereosinophilic syndrome/chronic eosinophilic leukemia, aggressive systemic mastocytosis, and some myelodysplastic/myeloproliferative diseases.¹ A new precaution will be added to the drug's labeling about the occasional occurrence of severe congestive heart failure and left ventricular dysfunction.²

¹Gleevec® approved in the US for five rare life-threatening disorders with limited treatment options. Media Release, October 20, 2006. <http://www.novartis.com/>

² <http://www.fda.gov/medwatch/safety/2006/safety06.htm#Gleevec>

MedWatch ... Wyeth and the FDA notified healthcare professionals of revisions to the **Overdosage**/Human Experience section of the prescribing information for **Effexor[®]** (**venlafaxine HCl**), indicated for treatment of major depressive disorder. In postmarketing experience, there have been reports of overdose with venlafaxine, occurring predominantly in combination with alcohol and/or other drugs. Published retrospective studies report that venlafaxine overdose may be associated with an increased risk of fatal outcome compared to that observed with SSRI antidepressant products, but lower than that for tricyclic antidepressants. Healthcare professionals are advised to prescribe Effexor[®] and Effexor[®] XR in the smallest quantity of capsules consistent with good patient management to reduce the risk of overdose. Read the complete MedWatch 2006 Safety summary, including links to the Dear Healthcare Professional letter and revised label, at:

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

MedWatch ... Heartland Repack Services and the FDA notified healthcare professionals of a voluntary recall of all products containing a lot number beginning with "K" (example: K12345). Drugs repackaged by Heartland Repack Services are distributed through their own pharmacy services to Omnicare nursing homes and other institutional facilities. This recall was initiated due to potential for mislabeling and packaging mix-up.

Read the complete MedWatch 2006 Safety summary, including links to the recall notices and product list, at:

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

FROM THE MEDICAL LITERATURE ...

Shingles Vaccine for Seniors ... The Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices recently decided that people age 60 years or older should receive a single dose of the zoster vaccine, which became available this past summer (Zostavax[®] by Merck) . For more information go to the web site below.

<http://www.cdc.gov/od/oc/media/pressrel/r061026.htm>

FROM THE LAY LITERATURE about medicine ...

Disease Risk Calculator ... the Harvard Center for Cancer Prevention has a useful web site designed to provide a risk assessment of disease development for individual patients. It provides risk for 12 different cancers. In addition, it assesses risk for heart disease, stroke, diabetes and osteoporosis. In addition to standard questions about history, diseases, etc it also takes into account diet, exercise and various lifestyles. Check it out at www.yourdiseaserisk.com
Parker-Pope T. Web site tallies your risk of disease and tells you what you can do about it. *Wall Street Journal*. 2006 Oct 31; p. D1.

Evaluation ... According to a new survey released, the Pew Internet Project, three-quarters of the population that check the Internet for health information give any thought as to the quality of the site/information; even simple things like checking the source or the date. It would seem that if more people did this, they might not ask so many dumb questions when they wave the printout for "Dr. Good's Magical, Mystical Cure" and demand to know why you don't have it! The article also mentioned several health-related search engines that may also be helpful.

Web health info seekers tend not to check sources. *USA Today*. 2006 Oct 30.

http://www.usatoday.com/tech/news/2006-10-30-health-online_x.htm

To save on fuel, burn more of your own ... A study to be published in *Engineering Economist* has already been oft quoted, and numbers don't lie! According to the paper, if the average American weight was the same as in 1960 (approximately 24-25 lbs lighter than today), we would save about 1 billion gallons of gasoline, or about \$2.2 billion, per year. So, here is yet another reason to take the diet and exercise mantra to heart. Think about it as a blow for American independence from foreign oil!!

Lee C. To spend less on gas, lose the spare tire. *Washington Post*. 2006 Oct 26; p. A03.

<http://www.washingtonpost.com/wp-dyn/content/article/2006/10/25/AR2006102501776.html?referrer=email>

Never doubt the power of advertising ... Restless Legs Syndrome (RLS) was a very little known problem a couple of years ago, but thanks to GlaxoSmithKline, few people have NOT heard of it. It is an interesting story of how the pharmaceutical company, investigating their drug **Requip® (ropinirole)** for Parkinson's heard of some physicians using it for RLS. Now the drug's \$500 million in sales is due more to use with RLS (approved for RLS in May 2005) than Parkinson's Disease. This happened through a thorough and well coordinated advertising blitz to both health professionals and consumers. Some call this "creating a market" and others call it "disease mongering." You be the judge.

Whalen J. How Glaxo marketed an ailment. *Wall Street Journal*. 2006 Oct 25.

and never doubt the power of direct marketing ... Off-label prescribing of **Actiq®** (fentanyl oral transmucosal by Cephalon) is apparently very high. It is indicated for pain relief in cancer patients, but it is prescribed for many other types of pain and the company is under investigation for inappropriately marketing the off-label uses in non-cancer related pain; Cephalon denies the allegations. The flavored lozenges on a stick make the medicine go down very easily; and diversion may start to be a problem. One street name is "perc-a-pop."

Carreyrou J. Narcotic 'lollipop' becomes big seller despite FDA curbs. *Wall Street Journal*. 2006 Nov 3; p. A1.

Update ...

Residencies/Positions ... There are several notices/brochures posted in the Drug Information Center for residencies and recruitment. As we receive them, they will be posted there. The most recent ones are:

- Drug information residency at the University of Kansas Hospital in Kansas City, KS.
- Drug Information Residency at AstraZeneca, based in Wilmington, DE
- Drug Information Residencies (2) at Mercer University/Solvay Pharmaceuticals, Atlanta
- Positions at Sacred Heart Health System in the Pensacola, FL area.
- and more....

AUBURN HSOP FACULTY in the literature ...

- Loi-Braden MH. A collaborative effort for treating hypertension to target. *Alabama Pharmacy*. 2006 Sum/Fall;39:11-12.
- Pounders CL. Treatment of chronic non-malignant pain and the prevention of abuse, addiction, and diversion: A balancing act. *Alabama Pharmacy*. 2006 Sum/Fall;39:13-14.
- Wells S, Olin BR. Will Ranexa® (ranolazine) change treatment of chronic angina? *Alabama Pharmacy*. 2006 Sum/Fall;39:15-17.

NEW RESOURCES in the DILRC ...

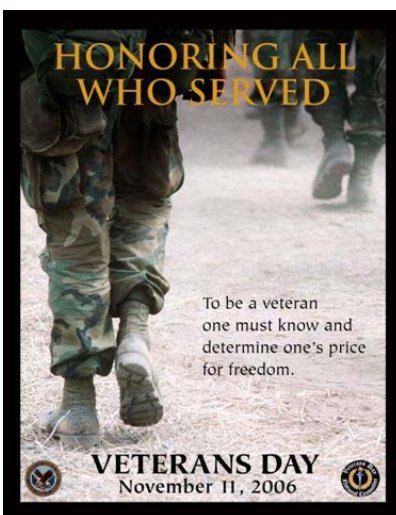
- Bartlett JD, ed. *Ophthalmic Drug Facts*. 18th ed. St. Louis: Facts and Comparisons/Wolters Kluwer Health, 2007.
- Lacy CR, Armstrong LL, Goldman MP, Lance LL. *Drug Information Handbook, 2006-2007*. 14th ed. Hudson, OH: Lexi-Comp, Inc., 2006.
- Taketomo CK, Hodding JH, Kraus DM. *Pediatric Dosage Handbook, 2006-2007*. 13th ed. Hudson, OH: Lexi-Comp, Inc., 2006.
- O'Neil MJ, ed. *The Merck Index: An encyclopedia of chemicals, drugs and biologicals*. 14th ed. Whitehouse Station, NJ: Merck & Co, Inc., 2006.
- Schiff ER, Sorrell MF, Maddrey WC, eds. *Schiff's Diseases of the Liver*. 10th ed. 2 vols. Baltimore: Lippincott Williams & Wilkins, 2007.

TIMELY TOP TECH TIP ...

The Pharmacist Activist is a new, electronic newsletter first published in January 2006. Each issue includes an editorial on a topic that is important for the profession of pharmacy, as well as a review of a new drug that includes a comparison of the new drug with previously marketed drugs that are most similar in activity, and a New Drug Comparison Rating (NDCR) for the new drug. This newsletter is written by Daniel A. Hussar of the faculty of the Philadelphia College of Pharmacy at the University of the Sciences in Philadelphia. Dr. Hussar is a respected pharmacy educator whose opinions and reviews are well worth reading. *The Pharmacist Activist* is **FREE** via e-mail to interested pharmacists and pharmacy students who request a complimentary subscription by signing up at the [Subscription](#) page.



The last “dose” ...



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