

AU InforMed

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Key Inforbits

- Vimpat[®] and Toviaz[™], new drugs!
- New guidelines for GERD
- Inhaled corticosteroids still a problem
- Indirectly-to-consumer advertising
- Salvia divinorum – why?
- Veteran's Day, November 11

NEW DRUGS, and other related stuff ...

New Drug ... (10/28/2008) The FDA has approved **lacosamide (Vimpat[®])** by UCB) for adjunctive therapy for partial-onset seizures in patients ≥ 17 years old. Its mechanism of action is thought to include reducing sodium channel over-activity in the central nervous system by prolonging the longer lasting resting state of the channel. The product is initially classified as a controlled substance but this is under further review. Vimpat[®] is available as oral tablets 50, 100, 150, and 200 mg strengths; it is also available as a parenteral product as 200 mg/20 mL. It is expected to be available in early 2009.

<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm> (Drugs@FDA – label available)

<http://hugin.info/133973/R/1264231/277752.pdf> (UCB press release)

New Drug ... (10/31/2008) The FDA has approved a new drug to help patients suffering from overactive bladder (OAB). **Fesoterodine fumarate (Toviaz[™])** by Schwarz Pharma of Zwickau, Germany; distributed by Pfizer Inc. of N.Y.) works by relaxing the smooth muscle tissue of the bladder, thus reducing the urinary frequency, urge to urinate, and sudden urinary incontinence (leakage of urine), that are characteristic symptoms of OAB. Toviaz[™] will be available as an extended release tablet in either 4 mg or 8 mg dosage strengths for adults. It is to be administered once daily. The recommended starting dose is 4 mg, which can be increased to 8 mg if needed. Common side effects have included dry mouth and constipation. Less frequently dry eyes and trouble emptying the bladder.

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01910.html>

New Generic ... **Keppra[®] (levetiracetam)** in 250 mg, 500 mg and 750 mg tablets is now available by Mylan Inc. The U.S. patent on the drug expires in January 2009 and UCB, the manufacturer of Keppra[®], will maintain the exclusive right to market Keppra[®] for pediatric use until that time.

<http://money.cnn.com/news/newsfeeds/articles/apwire/7fe5411f36a6e99dda888fa119ffe3e8.htm>

MedWatch ... (10/16/2008) Ethex Corp and the FDA announced a voluntary **recall of three lots of Dextroamphetamine Sulfate 5mg tablets**. The product was recalled due to the potential presence of oversized tablets that may contain as much as twice the labeled amount of the active ingredient. Taking a higher than expected dose of Dextroamphetamine Sulfate may be associated with an increased risk of adverse effects such as tachycardia, hypertension, tremors, decreased appetite, headache, insomnia, dizziness, blurred vision, stomach upset, and dry mouth.

Consumers and their caregivers should not use any Dextroamphetamine Sulfate tablets that appear to be oversized and should consult their healthcare professional with any questions. Read the entire 2008 MedWatch Safety Summary, including a link to the manufacturer's recall notice regarding the above issue at:

<http://www.fda.gov/medwatch/safety/2008/safety08.htm#Dextroamphetamine>

MedWatch ... (10/17/2008) The FDA announced extensive labeling changes, including a Boxed Warning, to highlight the risks of **life-threatening infections**, including bacterial sepsis, viral meningitis, invasive fungal disease, progressive multifocal leukoencephalopathy and other opportunistic infections with the use of **Raptiva[®] (efalizumab)**. Also described is a potential risk for the permanent suppression of the immune system with repeat administration of Raptiva[®] in children. Raptiva[®] is not approved for children under 18 years of age. Health care professionals should monitor patients treated with Raptiva[®] for the signs and symptoms of these adverse events and also instruct patients to report any such signs and symptoms to them without delay. Patients with pre-existing infections or who have a compromised immune system should notify their health care professional before beginning treatment with Raptiva[®].

Read the complete MedWatch 2008 Safety summary, including links to the FDA press release and the revised prescribing information, at:

<http://www.fda.gov/medwatch/safety/2008/safety08.htm#Raptiva>

MedWatch ... (11/6/2008) Covidien and FDA announced a recall of ReliOn sterile, single-use, disposable, hypodermic syringes with permanently affixed hypodermic needles. The **mislabeled syringe may result in patients receiving an overdose** of as much as 2.5 times the intended dose. These syringes are sold only by Wal-Mart or Sam's Club pharmacies under the ReliOn name. The recall applies only to lot number 813900. The product was distributed from Aug. 1, 2008 until Oct. 8, 2008, and includes 471,000 individual syringes in 4,710 boxes. FDA urges patients and health care professionals to check syringe packaging carefully for products with this lot number, not to use the product, and return the product to the pharmacy for replacement.

Read the complete MedWatch 2008 Safety summary, including a link to the FDA press release, at: <http://www.fda.gov/medwatch/safety/2008/safety08.htm#ReliOn>

FROM THE MEDICAL LITERATURE ...

Inhaled corticosteroids still a problem ... Inhaled corticosteroids (ICS) are commonly used drugs and one perceived benefit is fewer adverse effects. However, these agents are not devoid of problems. In addition to other documented problems such as osteoporosis and Cushing's syndrome, high dose ICS may also cause adrenal insufficiency. In a survey of relevant specialists in France (n=11,783), 46 cases of adrenal insufficiency associated with high-dose ICS were identified. While this represents a small incidence, it should remain on the mental monitoring list for these patients.

Molimard M, Girodet P-O, Pollet C, Fourrier-Réglat A, Daveluy A, Haramburu F, Fayon M, Tabarin A. Inhaled corticosteroids and adrenal insufficiency: Prevalence and clinical presentation. *Drug Safety*. 2008;31(9):769-774.

GERD Guidelines ... The American Gastroenterological Association has laid out its medical position on the management of gastroesophageal reflux disease (GERD) in the form of evidence-based evaluations of 12 questions. Each question was assessed using the current literature and the conclusions weighed against the U.S. Preventive Services Task Force (USPSTF) grades. One question addresses antisecretory therapies which received one of the highest grades, stating proton pump inhibitors (PPIs) are more effective than



histamine₂ receptor antagonists (H₂RA) which are more effective than placebo. Metoclopramide was judged ineffective in this condition.

American Gastroenterological Association Institute Medical Position Panel. American Gastroenterological Association Medical Position Statement on the Management of Gastroesophageal Reflux Disease. *Gastroenterology*. 2008 Oct;135(4):1383-1391.

Reviews of Note ...

- Heard KJ. Acetylcysteine for acetaminophen poisoning. *N Engl J Med*. 2008 Jul 17;359(3):285-292.
- Jarvis CI, Lynch AM, Morin AK. Management strategies for premenstrual syndrome/premenstrual dysphoric disorder. *Ann Pharmacother*. 2008 Jul/Aug;42(7/8):967-978.
- Abels M, Solitar BM, Pillinger MH, Abeles AM. Update on fibromyalgia therapy. *Am J Med*. 2008 Jul;121:555-561.
- Sebba A. Tocilizumab: The first interleukin-6-receptor inhibitor. *Am J Health-Syst Pharm*. 2008 Aug 1;65:1413-1418.
- Shoback D. Hypoparathyroidism. *N Engl J Med*. 2008 Jul 24;359(4):391-403.


FROM THE LAY LITERATURE about medicine ...

Direct-to-Consumer Ads – a New Approach ... This was highlighted during the Olympics in August. In order not to have to spend valuable and expensive time on TV commercials listing



required warnings about their drugs, some companies are exploring the “unbranded” approach. If a drug name is not mentioned specifically, all the warnings and side effect information is not required to be presented. This was exemplified by Pfizer’s ad for Chantix[®] (varenicline). The ad presented only an antismoking message and referred viewers to Mytimetoquit.com. At the site, the drug name, the message, and required full disclosure, is given. Watch for more.

Mundy A. Making a name for drugs without using their names: Some ads highlight only web addresses so side effects don’t have to be listed. *Wall Street Journal*. 2008 Aug 29.

Salvia divinorum – making a name ... a relatively newly discovered substance (at least to our substantial drug-seeking culture), salvia divinorum is considered one of the world’s most potent hallucinogens. Originally used by Mazatec shamans in Mexico, “YouTube” now has many clips of people taking this drug and acting like a “...total idiot.” Some states are actively pursuing regulation of the substance and it may reach the level of federal regulation. There is, of course, debate as to whether it should be regulated, but users are their own worst enemy when posting to the Internet and a common warning is to have a “sober sitter” when using the drug. Several deaths have been associated with taking it, commonly salvia-induced poor judgment (car accidents, gun-shot accidents, etc). Researchers are actively pursuing programs to divine useful pharmacology and they worry added regulation will hamper their efforts. What is the attraction!?! 

Sack K, McDonald B. Popularity of a hallucinogen may thwart its medical uses. *New York Times*. 2008 Sep 9. http://www.nytimes.com/2008/09/09/us/09salvia.html?_r=1&ref=health&oref=slogin

AUBURN HSOP FACULTY and STUDENTS in the literature ...

- Fox BI, Felkey BG. Wireless-friendly web sites that support daily activities. Hosp Pharm. 2008 Sep;43:759-761.
- Fox BI, Felkey BG. Automating medication reconciliation. Hosp Pharm. 2008 Oct;43:843-844.
- Wargo KA, Centor RM. ABCs of ABGs: A guide to interpreting acid-base disorders. Hosp Pharm. 2008 Oct;43(10):808-815.
- Wargo KA. Clinical judgment: To renally dose adjust antimicrobials or not. Pharmacotherapy. 2008 Oct;28(10):281e-283e.
- DeRuiter J, Holston PL. New drug review 2008. US Pharmacist. 2008 Oct;33(10):30-36, 41-2, 44.

Update ...

Health and Safety for College Students ... The Centers for Disease Control and Prevention (CDC) has a web site designed for college students. There is a variety of information covering eating habits to vaccinations. Check it out – it may help you or a loved one. Learn more about [college health and safety issues](#), including ways to:

Improve eating habits; Avoid fatigue and sleep deprivation; Maintain mental health; Avoid substance use; Have healthy relationships and prevent sexual violence; Prevent sexually transmitted diseases.

And More Information on:

[College Health and Safety](#)

[Tips for College Health and Safety Podcast](#) (🔊 3:18 minutes)

[College Life Health-e-Cards](#)

[Education: College Students](#)

[Bacterial Meningitis in College Students](#)

[Spring Break Health and Safety Tips](#)

[Vaccines: College Students and Young Adults](#)

<http://www.cdc.gov/Features/CollegeHealth/>



The last “dose” ...

“As we express our gratitude, we must never forget that the highest appreciation is not to utter words, but to live by them.”

~John Fitzgerald Kennedy [1917 - 1963]

Veteran's Day, November 11, 2008

<http://www1.va.gov/opa/vetsday/vetdayhistory.asp> [History of Veteran's Day]



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>

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