

AU InforMed

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Key Inforbits

- New drug and new dose form
- Metoprolol succinate ↔ tartrate switching
- Fake drugs a real problem
- Progress in breast cancer prevention
- Horses vs. Zebras in ADRs
- It always works in the right patient

NEW DRUGS, and other related stuff ...

New Drug (sort of) ... (1/30/2009) The FDA has approved dexlansoprazole (Kapidex™ by Takeda Pharmaceuticals North America, Inc) delayed release capsules, for the once-daily, oral treatment of heartburn associated with symptomatic non-erosive Gastroesophageal Reflux Disease (GERD), the healing of erosive esophagitis (EE) and the maintenance of healed EE. Kapidex™ (30 mg and 60 mg) is the first proton pump inhibitor (PPI) with a Dual Delayed Release™ (DDR) formulation designed to provide two separate releases of medication. Dexlansoprazole is an enantiomer of the parent compound, lansoprazole and studies show it to be more effective than placebo and equivalent to its parent.

<https://www.kapidex.com/default.aspx> (Manufacturer web site with package labeling)

New Dose Form / Indication ... (2/3/2009) The FDA has approved **calcitriol ointment (Vectical™ Ointment)** by Galderma Laboratories, L.P.) 3mcg/g, a unique vitamin D3 product for the treatment of mild-to-moderate plaque psoriasis in adults. Approval was based on two 8-week studies of >800 patients that compared twice-daily doses of Vectical™ Ointment with a vehicle treatment in mild-to-moderate plaque psoriasis. By the end of the study, 34% of patients achieved treatment success compared to 22% of those treated with vehicle. Adverse events were similar in both groups and included lab test abnormality, urine abnormality, psoriasis, hypercalciuria, pruritus and skin discomfort. Topical treatment is typically managed by corticosteroids, which are generally not indicated for long-term use, or other vitamin D products, which may be irritating when applied to sensitive skin fold areas. Vectical™ Ointment will be available by prescription in pharmacies in the first quarter of 2009.

<http://www.galdermausa.com/NewsAndMedia/PressRelease27.aspx> (Manufacturer Press Release)

<http://www.vectical.com/> (Product site with full prescribing information)

Darvon® banned? ... (1/30/2009) An FDA advisory panel voted 14-12 to recommend the ban of Darvon® (propoxyphene) and its combinations (Darvocet®) from the U.S. market. The move was based on a petition from Public Citizen, a consumer watch dog group, last fall although the request originally began in the 1970s. The basic argument is that propoxyphene is a minimally effective analgesic but with all the potent dangers of a narcotic, including dependence and many deaths due to accidental or intentional overdose. However, it remains a very popular drug (top 25), so the recommendation may not be a slam-dunk.

Associated Press. Health advisors recommend ban on Darvon. USA Today. January 31, 2009.

http://www.usatoday.com/news/health/2009-01-30-darvon_N.htm

MedWatch ... (2/4/2009) The FDA is aware of a recently published retrospective medical record review of 73 patients who receive **Drotrecogin alfa (activated) (Xigris[®] by Eli Lilly)**, indicated for the reduction of mortality in adult patients with severe sepsis (Gentry et al.; Crit Care Med 2009). The study reported an increased risk of serious bleeding and death in patients with sepsis and baseline bleeding risk factors who received this product. **Serious bleeding events** occurred in 7 of 20 patients (35%) with a bleeding risk factor vs. only 2 of 53 (3.8%) patients without bleeding risk factors. These findings are consistent with the current product label. The FDA is working with the manufacturer to further evaluate this information concerning Xigris[®]. The FDA urges both healthcare professionals and patients to report side effects from the use of Xigris[®] to the FDA's MedWatch Adverse Event Reporting program.

Read the complete MedWatch 2009 Safety summary, including links to the Early Communication and the Prescribing Information, at:

<http://www.fda.gov/medwatch/safety/2009/safety09.htm#Xigris>

MedWatch ... (2/4/2009) The **Ethex Corporation has expanded its nationwide recall** of products to include various prescription prenatal vitamin and iron supplement products. This is an extension of the MedWatch alert of January 27, 2009. To see this previous alert and a complete list of products being recalled, click on the link below.

Read the MedWatch 2009 safety summary, including links to the Ethex Press Releases, at

<http://www.fda.gov/medwatch/safety/2009/safety09.htm#Ethex>

FROM THE MEDICAL LITERATURE ...

Metoprolol shortage and conversion between products ... There is a shortage of metoprolol succinate (Toprol-XL[®]) due to manufacturing issues and recalls, and patients are being switched to metoprolol tartrate (Lopressor[®]). There are four suppliers of metoprolol succinate to the US market: The generic form of metoprolol succinate is produced by Ethex, Par, and Sandoz, while Astra-Zeneca is the supplier of Toprol-XL[®]. In September 2008, Sandoz recalled metoprolol-extended release tablets and they have since been on back order. To further add to the shortage, KV Pharmaceuticals, which markets prescription medications through Ethex, suspended shipments in December 2008 of all FDA approved drug products in tablet form due to manufacturing issues. Due to this shortage of metoprolol succinate, many clinicians are



switching their patients to metoprolol tartrate (Lopressor[®]). Metoprolol succinate is a once daily formulation and metoprolol tartrate is usually dosed twice daily. If switching between the drugs, the same total daily dose should be used. For example, if a patient is currently taking metoprolol succinate 50 mg once daily and they are switched to metoprolol tartrate, their new dosing regimen will be metoprolol tartrate 25 mg twice daily. *Scott Donald, Pharm.D. Candidate*

- Lacy CF, Armstrong LL, Goldman MP, Lance LL, eds. Drug Information Handbook. 17th ed. Hudson, OH; Lexi-Comp, 2008: 1027-1028.
- Drug Shortage Product Bulletin [Internet]. Drug Information Service (University of Utah) ASHP; January 26, 2009 [cited 2009 Feb 3]. Available from: <http://www.ashp.org/Import/PRACTICEANDPOLICY/PracticeResourceCenters/DrugShortages/GettingStarted/CurrentShortages/Bulletin.aspx?id=507> .
- Ethex Corporation Product Recall [Internet]. FDA Medwatch; January 27, 2009 [cited 2009 Feb 4]. Available from: <http://www.fda.gov/medwatch/safety/2009/safety09.htm#Ethex> .
- KV Pharmaceutical Voluntarily Suspends All Shipments of its Approved Tablet-form Drugs [Internet]. Press Release, KV Pharmaceuticals; December 23, 2008 [cited 2009 Feb 3]. Available from: http://www.kvpharmaceutical.com/news_center_article.aspx?articleid=276 .

Fake Drugs ... An editorial brings our attention back to the problem of counterfeit drugs. The thrust of the article concerns the sale of prescription drugs over the Internet. According to the article, approximately 62% of the drugs offered for sale in this fashion are fake. Effects could range from simply no effect, to disappointment for lack of effect, to dangerous if the drugs are used for serious disease such as cancer, hypertension, or diabetes, or actual harmful ingredients. The largest single market (big surprise!) are the phosphodiesterase 5 inhibitors (eg, Viagra® and relatives) sporting up to 15,000 web sites. In addition, all of these sites are profit-driven and often may support organized crime and perhaps even terrorist groups. An obvious tip-off is the sale of prescription drugs without a prescription. The old adage remains current, 'if it seems to be too good to be true, it probably is.'



Jackson G. Faking it: the dangers of counterfeit medicine on the internet. *Int J Clin Pract.* 2009 Feb;63(2):181.

Breast cancer reduction ... A follow up study of the Women's Health Initiative trial that linked increased breast cancer with hormone replacement therapy (HRT) with estrogen+progesterin in 2002, was reported. Investigators conducted an observation-study cohort to examine the effects of decreasing HRT use on the incidence of breast cancer. They found that the risk of breast cancer decreased considerably after discontinuation of the HRT. Another victory for evidence-based medicine!



Chlebowski RT, Kuller LH, Prentice RL, Stefanick ML, Manson JE, Gass M, et al for the WHI Investigators. Breast cancer after use of estrogen plus progesterin in postmenopausal women. *N Engl J Med.* 2009 Feb 5;360(6):573-587.

Reviews of Note ...

- Lichtenstein G. Bowel preparations for colonoscopy: A review. *Am J Health-Syst Pharm.* 2009 Jan 1;66:27-37.
- Naldi L, Rebora A. Seborrheic dermatitis. *N Engl J Med.* 2009 Jan 22;360:387-396.
- Williams JS, Brown SM, Conlin PR. Blood-pressure measurement. *N Engl J Med.* 2009 Jan 29;360(5):e6.
- Morris MI. Posaconazole: A new oral antifungal agent with an expanded spectrum of activity. *Am J Health-Syst Pharm.* 2009 Feb 1;66:225-236.
- Byerly WG. Working with the institutional review board. *Am J Health-Syst Pharm.* 2009 Jan 15;66:176-184.
- Nehra A. Erectile dysfunction and cardiovascular disease: Efficacy and safety of phosphodiesterase type 5 inhibitors in men with both conditions. *Mayo Clin Proc.* 2009 Feb;84(2):139-148.
- Paige NM, Nagami GT. The top 10 things nephrologists wish every primary care physician knew. *Mayo Clin Proc.* 2009 Feb;84(2):180-186.
- Min B, White CM. A review of critical differences among loop, thiazide, and thiazide-like diuretics. *Hosp Pharm.* 2009 Feb;44(2):129-149.
- Cortese MM, Parashar UD. Prevention of rotavirus gastroenteritis among infants and children: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR.* 2009 Feb 6;58(RR02):1-25.

FROM THE LAY LITERATURE about medicine ...

Case study of a rare adverse event ... An interesting article that chronicles a patient's journey through the medical system where the sound of hooves was consistently assumed to be horses, but in this case turned out to be zebras. It is a good reminder that some of those rare side effects we read about actually happen once in a



while. This patient developed sudden onset headaches that were intractable to standard, even extraordinary therapies, and always written off as a migraine. As it turns out the cause was due to a common drug.

Boodman SG. A headache that didn't go away. Washington Post. February 3, 2009; HE01.

<http://www.washingtonpost.com/wp-dyn/content/article/2009/02/02/AR2009020202209.html>

AUBURN HSOP FACULTY and STUDENTS in the literature ...

- Felkey BG. Web 2.0: Understanding opportunities for community pharmacy as the online world races ahead. *America's Pharmacist*. 2009 Feb;131(2):14-18.
Also includes picture on the cover page.
- Felkey BG, Fox BI. Are personal health records on your pharmacy department's radar screen? *Hosp Pharm*. 2009 Feb;44(2):191-192.

NEW RESOURCES in the DILRC ...

- Sajatovic M, Ramirez LF. *Rating Scales in Mental Health*. 2nd ed. Hudson, OH: Lexi-Comp, Inc, 2003.
- Jacobs DS, DeMott WR, Oxley DK. *Jacobs & DeMott Laboratory Test Handbook*. 5th ed. Hudson, OH: Lexi-Comp, Inc, 2001.
- Donnelly AJ, Baughman VL, Gonzales JP, Golembiewski J, Tomsik EA. *Anesthesiology & Critical Care Drug Handbook, 2008-2009*. 8th ed. , OH: Lexi-Comp, Inc, 2008.
- Lacy CF, Armstrong LL, Goldman MP, Lance LL. *Drug Information Handbook, 2008-2009*. 17th ed. Hudson, OH: Lexi-Comp, Inc, 2008.
- Desselle SP, Zgarrick DP. *Pharmacy Management: Essentials for All Practice Settings*. 2nd ed. NY: McGraw-Hill, 2009. \$52.95
- Koda-Kimble MA, Young LY, Alldredge BK, Corelli RL, Guglielmo BJ, Kradjan WA, Williams BR, eds. *Applied Therapeutics: The Clinical Use of Drugs*. 9th ed. Baltimore: Lippincott, Williams and Wilkins, 2009.



The last "dose" ...



"Go Red For Women" Join with millions of women, as well as companies, organizations and cities across America on **National Wear Red Day, Friday, Feb. 6, 2009**. By wearing red and making a donation, you'll help the American Heart Association support ongoing research and education about women and heart disease. The color red and the red dress now stand for the ability all women have to improve their heart health and live stronger, longer lives. http://www.goredforwomen.org/national_wear_red_day.aspx

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

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Bernie R. Olin, Pharm.D., Director