

AU InforMed

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Key Inforbits

- 3 new drugs, new dose form, 1Rx cosmetic
- More evidence – generics just as good ...
- OTC and supplement interactions, too
- 10 medical missteps to watch for ...
- Jan 1 – changes in pharmaceutical promotion
- Tablets are dangerous

NEW DRUGS, and other related stuff ...

New Drug ... (12/24/2008) The FDA has approved the injectable drug **degarelix** (manufactured for Ferring Pharmaceuticals Inc. by Rentschler Biotechnologie GmbH, Laupheim, Germany), the first new drug in several years for advanced prostate cancer. It belongs to a class of agents called gonadotropin releasing hormone (GnRH) receptor inhibitors. These agents slow the growth and progression of prostate cancer by suppressing testosterone, which plays an important role in the continued growth of prostate cancer. Several treatment options exist for different stages of prostate cancer including observation, prostatectomy (surgical removal of the prostate gland), radiation therapy, chemotherapy, and hormone therapy with agents that affect GnRH receptors. The most frequently reported adverse reactions in the clinical study included injection site reactions (pain, redness, and swelling), hot flashes, increased weight, fatigue, and increases in some liver enzymes. Trade name is to be determined.

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01935.html>

New (pro)Drug ... (12/14/2008) The FDA has approved **Lusedra™ (fospropofol disodium** by Eisai Corp.) Injection, an intravenous sedative-hypnotic agent for monitored anesthesia care sedation in adult patients undergoing diagnostic or therapeutic procedures. Fospropofol disodium is a water-soluble prodrug of propofol that, after intravenous injection, is converted by alkaline phosphatase enzymes in the body into propofol. The FDA requires that Lusedra™ be used only by persons trained in the administration of general anesthesia and that all patients should be continuously monitored by persons not involved in the conduct of the procedure. The FDA has also recommended that Lusedra™ be classified as a controlled substance. A final scheduling decision is expected from the U.S. Drug Enforcement Administration (DEA) and once Lusedra™ receives final scheduling designation, the label will be amended.

http://www.eisai.com/view_press_release.asp?ID=147&press=206 (Manufacturer press release)

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01934.html> (FDA News Release)

New Contrast Agent ... (12/22/2008) The FDA has approved a novel blood pool magnetic resonance angiography (MRA) agent, **Vasovist® (gadofosveset trisodium** by EPIX Pharmaceuticals), to evaluate aortoiliac occlusive disease (AIOD) in adults with known or suspected peripheral vascular disease. AIOD occurs when iliac arteries become narrowed or blocked and may prevent the sufficient transport of oxygen and/or blood throughout the body. Vasovist® is the first contrast agent approved for marketing in the United States for use with MRA, a non-invasive modality for imaging blood vessels.

<http://investor.epixpharma.com/phoenix.zhtml?c=91717&p=irol-newsArticle&ID=1238529&highlight=> (Manufacturer press release)

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01934.html> (FDA News Release)

New Dose Form ... (12/22/2008) The FDA has approved **Zolpimist™ (zolpidem tartrate) 5 mg and 10 mg Oral Spray** by NovaDel Pharma Inc. for the short-term treatment of insomnia characterized by difficulties with sleep initiation. Zolpimist™ is NovaDel's second product approved by the FDA that uses NovaDel's proprietary NovaMist™ oral spray technology. Due to its rapid onset of action, patients should take Zolpimist™ immediately before bedtime and be prepared to get a full night's sleep (7-8 hours).

<http://www.integratir.com/newsrelease.asp?news=2131022053&ticker=NVD&lang=EN>
(Manufacturer's press release)

New Indication ... (12/27/2008) **Latisse™ (bimatoprost by Allergan)** ophthalmic solution 0.3 mg/mL has been approved by the FDA to treat **hypotrichosis of the eyelashes** by increasing their growth including length, thickness and darkness. It is a prostaglandin analog, originally indicated for glaucoma. The "positive" effect on eyelashes was noticed and many physicians have been prescribing it for such. Latisse™ is still a prescription product, although for a cosmetic use; it will retail for \$120/month. Results occur in 8 to 16 weeks. Once discontinued the eyelashes will recede to original status. Discoloration of the iris is one of the side effects.

<http://www.latisse.com/> (Manufacturer web site with package insert)

Rundle RL. Eyelash enhancer gains approval: FDA clears Allergan's glaucoma drug for marketing as cosmetic treatment. Wall Street Journal. December 27, 2008.

<http://online.wsj.com/article/SB123030281285935451.html?mod=djemHL> (subscription only)

MedWatch ... (12/2/2008) **Innohep in Renal Insufficiency Study (IRIS)** was stopped in February, 2008 by the study's Data Safety Monitoring Committee because of an interim finding of an increase in all-cause mortality in patients who received Innohep. Information on the study is still being collected and analyzed. In July 2008, the company revised the prescribing information to restrict the use of Innohep in patients 90 years of age or older. FDA is concerned that the preliminary data from the IRIS study suggest that the increased risk of mortality is not limited only to patients 90 years of age or older. Healthcare professionals should consider the use of alternative treatments to Innohep when treating elderly patients over 70 years of age with renal insufficiency and DVT, PE, or both. FDA anticipates submission of the final IRIS study report in January, 2009 and plans to complete its review soon thereafter.

Read the complete MedWatch 2008 Safety summary, including a link to the FDA

Communication, at: <http://www.fda.gov/medwatch/safety/2008/safety08.htm#Innohep>

MedWatch ... (12/9/2008) Hospira, Inc. notified healthcare professionals of a **recall of one lot (lot number 65-620-FW, expiration date May 1, 2010, NDC 0409-7902-09) of 20 mEq Potassium Chloride in 5% Dextrose and 0.45% Sodium Chloride Injection, USP in 1000 mL flexible plastic containers**. A small number of the containers may be incorrectly labeled with a bar code for 5% Dextrose Injection, USP (NDC 0409-7922-09). The affected lot was shipped to U.S. customers between July 2008 and September 2008. Healthcare facilities with an existing inventory should quarantine the product immediately and call Hospira Customer Care at 1-877-946-7747 for instructions on how to return it.

Read the MedWatch 2008 safety summary, including a link to the company's press release, at:

<http://www.fda.gov/medwatch/safety/2008/safety08.htm#20meqPotChlor>

FROM THE MEDICAL LITERATURE ...

Generic vs. Brand-name drugs ... In a meta-analysis, authors located 38 randomized, controlled trials that compared generic and brand-name cardiovascular drugs and analyzed the results for comparative efficacy. Of the 38 trials (including β -blockers, diuretics, calcium channel blockers, antiplatelet agents, statins, ACEIs, and α -blockers), 35 trials showed no evidence of brand-name superiority. Perhaps of more interest, the authors also located 43 editorials on the topic and 23 (53%) expressed a preference for the brand-name drug when making a prescribing choice. To paraphrase a saying, "I've made up my mind, don't confuse me with facts!"



Kesselheim AS, Misono AS, Lee JL, Stedman MR, Brookhart MA, Choudhry NK, Shrank WH. Clinical equivalence of generic and brand-name drugs used in cardiovascular disease: A systematic review and meta-analysis. *JAMA*. 2008 Dec 3;300(21):2514-2526.

It's not just the Rx's – don't forget the OTCs ... From the National Social Life, Health and Aging Project (NSHAP), a population-based survey of community-dwelling older adults in the US, 3005 individuals 57-85 years old were drawn. They were interviewed in-home and among other data, prescription drugs, over-the-counter medications and dietary supplements were recorded. There were 81% that took at least one drug, 42% used at least one OTC and 49% used at least one dietary supplement; 29% used at least 5 Rx's (highest in those over 75 years). Overall, 4% were at risk of a major drug-drug interaction (identified through Micromedex database); the most prevalent drugs were cardiovascular and the most common interaction culprit involved anticoagulants/antiplatelets.



Qato DM, Alexander GC, Conti RM, Johnson M, Schumm P, Lindau ST. Use of prescription and over-the-counter medications and dietary supplements among older adults in the United States. *JAMA*. 2008 Dec 24/31;300(24):2867-2878.

Reviews of Note ...

- Ogburn T, Voss C, eds. Women's Health (13 articles). *Med Clin N Am*. 2008 Sep;92(5):993-1305.
- Gross NJ. Chronic obstructive pulmonary disease: An evidence-based approach to treatment with a focus on anticholinergic bronchodilation. *Mayo Clin Proc*. 2008 Nov;83(11):1241-1250.
- Hayes JT, Ebbert JO. Varenicline for tobacco dependence. *N Engl J Med*. 2008 Nov 6;359:2018-2024.
- Marile PE, Plante LA. Venous thromboembolic disease and pregnancy. *N Engl J Med*. 2008 Nov 6;359:2025-2033.

FROM THE LAY LITERATURE about medicine ...

10 Medical Missteps ... according to one physician, here are 10 pitfalls to avoid as a prescriber and clinician. Four of these relate directly to drug therapy: Prescribing narcotics, patients on warfarin, side effects of "statins," and chronic medications (started but never stopped).



Two involve common pharmacist encounters: "Google abuse" and a health plan's fine print. In other words, pharmacists are heavily invested in daily patient care.

Advice from Dr. Haig: 10 Medical Missteps. *Time.com* November 2008.

http://www.time.com/time/specials/packages/article/0,28804,1847616_1847615_1847614,00.html

January 1, 2009 ... This is the date that voluntary restrictions on pharmaceutical company promotions goes into effect, limiting the “freebies” to physicians. In brief, it bans pens, pads, mugs, etc (dubbed noneducational gifts) but still allows catered lunches to offices, and payments for services (such as speaker’s bureau, ghost writing). Approximately 3 dozen companies have



agreed to abide by the restrictions. Various states already require reporting of payments to physicians and this may increase. Also, some medical schools, hospitals and health care organizations have limited or banned pharmaceutical promotion in their institutions. This has gained recent momentum via editorials in journals, and several studies that have refuted a common physician claim that such minor gifts have no influence on their prescribing habits. When the freebies dry up, we’ll see how it goes ...

Darcé K. New Rx: Minimize drug firm influence: Doctors, industry adopt stricter rules. San Diego Union-Tribune. December 22, 2008.

<http://www3.signonsandiego.com/stories/2008/dec/22/1n22pharma002651-doctors-industry-adopt-stricter-r/>

AUBURN HSOP FACULTY and STUDENTS in the literature ...

- Thomas SG, Hester EK, Duncan-Hewitt W, Villaume WA. A high-stakes assessment approach to applied pharmacokinetics instruction. *Am J Pharm Ed.* 2009;72(6): Article 146.

NEW RESOURCES in the DILRC ...

- Smith BT. *Concepts in Immunology and Immunotherapeutics*. 4th ed. Bethesda, MD: American Society of Health System Pharmacists, 2008.
- McNeil MJ. *ASHP’s Safety and Quality Pearls*. Bethesda, MD: American Society of Health System Pharmacists, 2008. \$35.00
- Gilbert DN, Moellering RC Jr, Eliopoulos GM, Sande MA, eds. *The Sanford Guide to Antimicrobial Therapy 2008*. 38th ed. Sperryville, VA: Antimicrobial Therapy, Inc., 2008.



The last “dose” ...

“100 years ago: The Abuse of the Tablet

The convenience of the tablet form of medication has doubtless developed in the medicine-taking public a dangerous contempt for potent drugs that has been bred of familiarity. This was recently exemplified by the case reported in our British contemporaries of a woman who took thirteen aspirin tablets between 3 pm one day and 10 am the next. She died of heart failure and, in accordance with the medical testimony, a verdict was returned of death accelerated by an overdose of aspirin. The very advantages convenience and portability, are in  that a tablet has in case of administration, themselves elements of danger, when drugs in this form are indiscriminately used by the public.

JAMA. 1908;51:2220, 2228.

Editor’s Note: JAMA 100 Years Ago is transcribed verbatim from articles published a century ago, unless otherwise noted.

JAMA 100 Years Ago Section Editor: Jennifer Reiling, Assistant Editor.

JAMA. 2008 Dec 24/31;300(24):2928.”

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

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