

AU InforMed

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Key Inforbits

- New indications and generics
- Vocabulary words
- New guidelines on diabetes screening
- Pharmacist benefits shown once again
- Flip-flops – Bad!
- New code of conduct from PhRMA

NEW DRUGS, and other related stuff ...

New Generic ... (6/30/2008) The FDA has approved the first **generics of risperidone** tablets (Risperdal[®] by Janssen). Risperidone is an atypical antipsychotic agent indicated for treatment of schizophrenia, bipolar disorder and other psychiatric conditions. The labeled indications may differ from Risperdal[®] as some are still protected by patents. Otherwise, labeling should be the same among the agents.

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01855.html>

New Indication ... (6/16/2008) The FDA has **approved duloxetine HCl (Cymbalta[®] by Eli Lilly) for the management of fibromyalgia**, a chronic widespread pain disorder. Cymbalta[®] is the first serotonin-norepinephrine reuptake inhibitor approved for reducing pain in patients with fibromyalgia. The fibromyalgia indication is the second FDA-approved use for Cymbalta[®] for a pain disorder, demonstrating the medication's analgesic effect.

<http://www.cymbalta.com/fibromyalgia.jsp>

MedWatch ... (7/16/2008) Roxane Laboratories, Inc. informed healthcare professionals of the **recall of two lots of Sodium Polystyrene Sulfonate Suspension**, USP, 15 g/60 mL Unit dose bottles (NDC 0054-0165-51; lot 856396A Exp April 2010, and lot 856693A Exp May 2010), a product used to treat hyperkalemia. A sample of one of the affected lots tested positive for a strain of yeast, which could potentially affect immunocompromised patients. Symptoms of a yeast infection range from thrush, skin rash, and blood infections. If patients develop an infection they should consult their physician. Pharmacists should determine if any of the referenced product has been dispensed and retrieve it. Additionally, pharmacists and wholesalers of the product should discontinue distribution and use of the referenced lots immediately and contact the manufacturer regarding returning the product. See the entire 2008 MedWatch Safety Summary, including a link to the manufacturer's recall notice regarding this issue at:

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

MedWatch ... (7/14/2008) Genentech, Inc. informed healthcare professionals of reports of several cases of **microangiopathic hemolytic anemia (MAHA) in patients with solid tumors receiving Avastin[®]** (bevacizumab) in combination with sunitinib malate (Sutent[®] by Pfizer). Avastin[®] is not approved for use in combination with sunitinib malate and this combination is not recommended. In a Phase I dose-escalation study 25 patients were studied combining Avastin[®] and sunitinib malate. There were 3 cohorts using a fixed dose of Avastin[®] at

10mg/kg/IV every 2 weeks and escalating doses of sunitinib that included 25, 37.5, and 50 mg orally daily given in a 4 weeks on/ 2 weeks off schedule. Five of 12 patients at the highest sunitinib dose level exhibited laboratory findings consistent with MAHA. Two of these cases were considered severe with evidence of thrombocytopenia, anemia, reticulocytosis, reductions in serum haptoglobin, schistocytes on peripheral smear, modest increases in serum creatinine levels, severe hypertension, reversible posterior leukoencephalopathy syndrome, and proteinuria. The findings in these 2 cases were reversible within 3 weeks upon discontinuation of both drugs without additional interventions. Healthcare professionals should report cases of MAHA or any serious adverse events suspected to be associated with the use of Avastin[®].

Read the entire 2008 MedWatch Safety Summary, including a link to the manufacturer's Dear Healthcare Provider Letter regarding this issue at:

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

MedWatch ... (7/10/2008) Genentech informed healthcare professionals that an increased number of complaints were received regarding **damaged and broken vials of Herceptin** 440 mg and BWHI (bacteriostatic water for injection) diluent. The affected vials are NDC# 50242-0134-68, List # 15534. Healthcare professionals should inspect cartons of the product for signs of leakage, cracks and other damage to the vials, observe the vials during reconstitution, and check for loss of vacuum in the vials. See the manufacturer's letter for specific details and recommendations, including instructions in the event a compromised vial is discovered.

Read the entire 2008 MedWatch Safety Summary, including a link to the manufacturer's Dear Healthcare Professional Letter regarding this issue at:

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

MedWatch ... (7/10/2008) FDA notified healthcare professionals that a **BOXED WARNING** and Medication Guide are to be added to the prescribing information to strengthen existing warnings about the increased risk of developing **tendinitis and tendon rupture in patients taking fluoroquinolones** for systemic use. This risk of tendinitis and tendon rupture is further increased in those over age 60, in kidney, heart, and lung transplant recipients, and with use of concomitant steroid therapy. Physicians should advise patients, at the first sign of tendon pain, swelling, or inflammation, to stop taking the fluoroquinolone, to avoid exercise and use of the affected area, and to promptly contact their doctor about changing to a non-fluoroquinolone antimicrobial drug. Limit selection of a fluoroquinolone for the treatment or prevention of an infection to those conditions that are proven or strongly suspected to be caused by bacteria. Read the complete MedWatch 2008 Safety Summary, including a link to the 'Information for Healthcare Professionals' page, at:

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

FROM THE MEDICAL LITERATURE ...



Vocabulary ... Cosmetovigilance ... “Vigilance system for adverse effects of cosmetic products.” Two articles describe early attempts to monitor cosmetic adverse effects in Italy and the European Union. The authors provide some interesting data regarding the incidence of adverse effects. There will be some significant differences between the EU and the US as to laws and regulations, but also many similarities. This may become more of a concern on this side of the pond in coming years. Sautebin L. Understanding the adverse effects of cosmetics: A pilot project in cosmetovigilance. *Drug Safety*. 2008;31(5):433-436.

Moretti U, Velo G. Cosmetovigilance: The ‘beautiful’ risk. *Drug Safety*. 2008;31(5):437-439.

Vocabulary ... Neat Mistakes ... “prescribing mistakes still occur but they are ‘neat’ because they can be easily read.” The term is attributed to pharmacist Tom Genco of New Jersey. It is in reference to electronic prescriptions (e-prescribing) where the prescription is printed out (avoiding the scribble problem) but still may contain errors, as any other prescription may. The lesson is that e-prescribing may eliminate penmanship problems but will not necessarily eliminate prescribing errors.

Hussar DA. Neat mistakes. *Pharmacist Activist*. 2008 May;3(5):2.

http://www.pharmacistactivist.com/2008/may_2008.shtml [Free subscription also available here]

Guidelines – Screening for Type 2 Diabetes ... The U.S. Preventive Services Task Force has issued a recommendation that those patients whose blood pressure exceeds 135/80 mmHg (treated or untreated) should be screened for type 2 diabetes mellitus. Based on pre-established criteria, 69 studies were evaluated. These randomized controlled trials were abstracted in a qualitative manner and a random-effects meta-analysis was performed on the effects of interventions in prediabetes for the incidence of diabetes. Despite the numerous studies, there is little direct clinical trial evidence to evaluate, as most came from subgroup analyses.

U.S. Preventive Services Task Force. Screening for type 2 diabetes mellitus in adults: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med*. 2008 Jun 3;148(11):846-854.

Norris SL, Kansagara D, Bougatsos C, Fu R. Screening for type 2 diabetes: A review of the evidence for the U.S. Preventive Services Task Force. *Ann Intern Med*. 2008 Jun 3;148(11):855-868.

Pharmacist intervention beneficial even over the Web ... A three-prong study compared 778 hypertensive patients in a usual care group; a group with Web access and blood pressure monitoring; and a third group where Web access and home blood pressure monitoring was supplemented with pharmacist care/monitoring, also over the Web. The group with the pharmacist monitoring had significantly better blood pressure readings over the course of one year than the other two groups. There are many potential limitations to this study and these are detailed in the paper as well as in an accompanying editorial. One small step at a time ...

Green BB, Cook AJ, Ralston JD, Fishman PA, Catz SL, Carlson J, et al. Effectiveness of home blood pressure monitoring, web communication, and pharmacist care on hypertension control: A randomized controlled trial.

JAMA. 2008 Jun 25;299(24):2857-2867.

Jones DW, Peterson ED. Improving hypertension control rates: Technology, people, or systems? *JAMA*. 2008 Jun 25;299(24):2896-2898.

Reviews of Note ...

- Passarella S, Duong M-T. Diagnosis and treatment of insomnia. *Am J Health-Syst Pharm*. 2008 May 15;65:927-934.
- Bieber T. Atopic Dermatitis. *N Engl J Med*. 2008 Apr 3;358(14):1483-1494.
- Baldwin CM, Lyseng-Williamson KA, Keam SJ. Meropenem: A review of its use in the treatment of serious bacterial infections. *Drugs*. 2008;68(6):803-838.
- Markman M. Pharmaceutical management of ovarian cancer. *Drugs*. 2008;68(6):771-789.
- Yang LPH, Keam SJ. Retapamulin: A review of its use in the management of impetigo and other uncomplicated superficial skin infections. *Drugs*. 2008;68(6):855-873.
- Schweiger TA, Zdanowicz MM. Vasopressin-receptor antagonists in heart failure. *Am J Health-Syst Pharm*. 2008 May 1;65:807-817.
- Verhamme KMC, Sturkenboom MCJM, Stricker BHCh, Bosch R. Drug-induced urinary retention: Incidence, management and prevention. *Drug Safety*. 2008;31(5):373-388.

- Eckel RH. Nonsurgical management of obesity in adults. N Engl J Med. 2008 May 1;358(18):1941-1950.

FROM THE LAY LITERATURE about medicine ...

Flip-flops – your mother was right! ... A study done by a biomechanics doctoral student from Auburn (War Eagle!) was presented at the annual meeting of the American College of Sports Medicine. This study has shown that the thong-style flip-flops, worn by virtually everyone under age 30, may be bad for you. Due to the subtle changes in walking necessary to keep the things on, especially over extended periods of time, pain and injury may result to feet, ankles and legs. This may also extend up to the hips and lower back. You've been warned.



Summer flip-flops may lead to foot pain. New York Times. 2008 June 5.

<http://well.blogs.nytimes.com/2008/06/05/summer-flip-flops-may-lead-to-foot-pain/>

PhRMA solves everything ... The Pharmaceutical Research and Manufacturers Association (PhRMA), the industry trade group, issued a new marketing code of ethics to address the concerns of health care professionals and patients concerning undue influence of the pharmaceutical industry on physician prescribing. Key features of the “Code” is that it is voluntary and unenforceable. It does seek to limit noneducational give-aways and extravagant meals, trips, etc. However, see again the key features above.

Johnson A. Drug group sets marketing code. Wall Street Journal. 2008 July 11.

AUBURN HSOP FACULTY and STUDENTS in the literature ...

- Wargo KA. Drug dosing in CKD – Comparing GFR equations and the role of the pharmacist: An expert interview with Kurt A. Wargo, PharmD, BCPS. MedScape Nephrology. 2008 Apr 23. <http://www.medscape.com/viewarticle/572994>
- Neighbors LJ, Olin BR. The role of long-acting β_2 agonists in asthma treatment. Alabama Pharmacist. 2008 Quart 1; 28-30.
- Carroll DN, Carroll DG. Interactions between warfarin and three commonly prescribed fluoroquinolones. Ann Pharmacother. 2008 May;42:680-685.
- Fox BI, Felkey BG. Considerations when upgrading your PDA/Smartphone. Hosp Pharm. 2008 May;43:421-422.



The last “dose” ...

The Summer looks out from her brazen tower,
Through the flashing bars of July.

-- Francis Thompson [1859 - 1907, English poet]

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

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