

AU InforMed

Volume 6 Number 23 (Issue 200)

Monday, November 3, 2008

Guest Editor: Barbara Paulison, Pharm.D. Candidate



Key Inforbits

- Reinforce pediatric dosage recommendations
- Pramlintide[®] for weight loss
- ACEIs vs. ARBs
- Increased deaths with Eprex[®]
- Medicare is not going to take it anymore!
- Political promises

NEW DRUGS, and other related stuff ...

New Drug ... (10/10/2008) The FDA has approved **Rapaflo[™]** (silodosin by Watson Pharmaceuticals Inc) capsules for the treatment of symptoms due to benign prostatic hyperplasia (BPH). Silodosin blocks the alpha-1 adrenoreceptors in the prostate, bladder, and urethra. This allows the smooth muscle in these tissues to relax, resulting in a reduction in BPH symptoms. Rapaflo[™] will be available in a once-daily capsule. An 8 mg daily dose is recommended for men who do not suffer from kidney or liver impairment. A 4 mg daily dose will be available for men with moderate kidney (renal) impairment. Rapaflo[™] is not recommended for men with severe kidney (renal) or liver (hepatic) impairment. The most common side effect with Rapaflo[™] is reduced or no semen during orgasm. This does not pose a safety concern and is reversible upon discontinuation. Other side effects included dizziness, light-headedness, diarrhea, orthostatic hypotension (drop in blood pressure upon standing), headache, nasopharyngitis (a contagious viral infection of the nose and upper portion of the throat), and nasal congestion.

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01902.html>

USP Develops Drug Error Database ... The United States Pharmacopeia (USP) has developed [Drug Error Finder](#), a free online tool for accessing drug names that have been identified with a medication error. The Website includes information on medication errors derived from the USP's most recent report, searchable by more than 1,400 drugs involved in look's alike and/or sound's alike errors. The site also lists drugs involved in other medication errors as well as specifying the severity of the error for which at least one report was received from the USP's Medication Errors Reporting Program. [To learn more, click here.](#)

MedWatch ... (9/4/2008) FDA notified healthcare professionals that pulmonary and disseminated histoplasmosis, coccidioidomycosis, blastomycosis and other opportunistic infections are not consistently recognized in patients taking tumor necrosis factor- α blockers (TNF blockers). Signs and symptoms of possible systemic fungal infection, include fever, malaise, weight loss, sweats, cough, dyspnea, and/or pulmonary infiltrates, or other serious systemic illness with or without concomitant shock. For patients at risk of histoplasmosis and other invasive fungal infections, clinicians should consider empiric antifungal treatment until the pathogen(s) are identified. Read the complete MedWatch 2008 Safety summary, including links to the Information for Healthcare Professionals page, FDA press release and previous MedWatch alert on these products, at: <http://www.fda.gov/medwatch/safety/2008/safety08.htm#TNF2>

MedWatch ... (9/11/2008) Genentech informed healthcare professionals of revisions to prescribing information for **Rituxan® (rituximab) regarding a case of progressive multifocal leukoencephalopathy (PML)** leading to death in a patient with rheumatoid arthritis. The patient developed a JC virus infection with resultant PML and death 18 months after taking the last dose of Rituxan®. Healthcare professionals treating patients with Rituxan® should consider PML in any patient presenting with new onset neurologic manifestations. Additionally, consultation with a neurologist, brain MRI and lumbar puncture should be considered as clinically indicated. Read the entire 2008 MedWatch Safety Summary, including a link to the manufacturer's Dear Healthcare Professional Letter and updated prescribing information for Rituxan regarding the above issue at: <http://www.fda.gov/medwatch/safety/2008/safety08.htm#Rituxan>

MedWatch ... (9/23/2008) OSI and Genentech notified healthcare professionals that cases of **hepatic failure and hepatorenal syndrome, including fatalities, have been reported during use of Tarceva® (erlotinib)**, particularly in patients with baseline hepatic impairment. Monitor patients with hepatic impairment receiving Tarceva® closely and use the product with extra caution in patients with total bilirubin >3x ULN. Dosing should be interrupted or discontinued if changes in liver function are severe, such as doubling of total bilirubin and/or tripling of transaminases in the setting of pretreatment values outside the normal range. Read the entire 2008 MedWatch Safety Summary, including links to the manufacturer's Dear Healthcare Provider Letter and the revised prescribing information for Tarceva, at: <http://www.fda.gov/medwatch/safety/2008/safety08.htm#Tarceva> .

MedWatch ... (10/9/2008) The FDA announced that the Consumer Healthcare Products Association (CHPA) is voluntarily modifying the product labels for consumers of **over the counter (OTC) cough and cold medicines to state "do not use" in children under 4 years of age**. FDA supports CHPA members to help prevent and reduce misuse and to better inform consumers about the safe and effective use of these products for children. Parents and care givers should adhere to the dosage instructions and warnings on the label that accompanies OTC cough and cold medications before giving the product to children, and should consult their healthcare professionals if they have any questions or concerns. Read entire 2008 MedWatch Safety Summaries, including link to FDA Press Release regarding the above issue at: <http://www.fda.gov/medwatch/safety/2008/safety08.htm#CoughCold>

FROM THE MEDICAL LITERATURE ...

Anti-diabetic agent may treat obesity ... Pramlintide (Symlin®), an anti-diabetic agent, was shown to help obese subjects achieve greater initial weight loss and enhanced long-term maintenance of weight loss. The study was a 4-month, double-blind, placebo-controlled, dose-ranging study in which 411 obese subjects were randomized to receive pramlintide (six arms: 120, 240, and 360 mcg, BID and TID) or placebo in addition to a structured lifestyle intervention program geared toward weight loss. By month 4, those in the pramlintide 120 mcg TID, and 360 mcg BID and TID groups achieved statistically significant reductions in absolute body weight versus placebo. The weight loss that occurred in the placebo group was subsequently gained back during a 12 month extension period. Weight loss was maintained or continued in all but the pramlintide 120 mcg BID arm. Weight loss during the 12 month extension was statistically significant with pramlintide 120 mcg TID, 240 mcg TID, 360 mcg BID and TID compared to placebo. Pramlintide was well tolerated with no significant safety concerns across doses. Smith SR, Aronne LJ, Burns CM, Kesty NC, Halseth AE, Weyer C. Sustained weight loss following 12-month pramlintide treatment as an adjunct to lifestyle intervention in obesity. *Diabetes Care* 2008;31:1816-1823.

Increasing incidence of Lyme disease ... The CDC recently released findings of Lyme disease reporting from 1992 to 2006. A total of 248,074 cases of Lyme disease were reported to the CDC by health departments in the 50 states, District of Columbia, and U.S. territories. The number of cases more than doubled from 1992 to 2006, with a disproportionately increased incidence among children aged 5-14 years and young males. These numbers make Lyme disease the most commonly reported vector-borne illness in the U.S. Most cases were located in the northeastern and north-central states. This report substantiates the need for targeted prevention strategies, early disease recognition and treatment, and a sustainable surveillance system.



Bacon RM, Kugeler KJ, Mead PS. Surveillance for Lyme Disease - United States, 1992–2006. MMWR. 2008 Oct 3;57(SS-10):1-9. <http://www.cdc.gov/mmwr/preview/mmwrhtml/ss5710a1.htm>

ARBs in patients intolerant to ACEIs ... The *Lancet* recently published a study analyzing the efficacy of an angiotensin receptor blocker, telmisartan (Micardis[®]), in patients intolerant to ACEIs. The study included 5,926 patients intolerant to ACEIs with established coronary artery, peripheral vascular, or cerebrovascular disease, or diabetes with end-organ damage. The participants were randomly assigned to receive either 80 mg of telmisartan or placebo. Telmisartan was well tolerated by study participants and modestly reduced the risk of the composite outcome of cardiovascular death, myocardial infarction, or stroke. However, the drug did not have a significant effect on the primary outcomes which included hospitalizations for heart failure. It was noted that the benefits of telmisartan were more evident after 6 months of therapy, suggesting longer treatment may be necessary to determine the full benefits of this drug.



The Telmisartan Randomised Assessment Study in ACE Intolerant subjects with cardiovascular Disease (TRANSCEND) Investigators. Effects of the angiotensin-receptor blocker telmisartan on cardiovascular events in high-risk patients intolerant to angiotensin-converting enzyme inhibitors: a randomised controlled trial. *Lancet* 2008; 372: 1174–1183.

Reviews of Note ...

- Jager RD, Mieler WF, Miller JW. Age-related macular degeneration. *N Engl J Med*. 2008 Jun 12;358(24):2606-2617.
- Croom KR, Plosker GL. Irbesartan: A review of its use in hypertension and diabetic nephropathy. *Drugs*. 2008;68(11):1543-1569.
- McKeage K, Blick SKA, Croxtall JD, Lyseng-Williamson KA, Keating GM. Esomeprazole: A review of its use in the management of gastric acid-related diseases in adults. *Drugs*. 2008;68(11):1571-1607.
- Daugherty KK. Aliskiren. *Am J Health-Syst Pharm*. 2008 Jul 15;65:1323-1332.

FROM THE LAY LITERATURE about medicine ...

Better flu vaccine ... U.S. health officials believe this year's flu vaccine will be a better match for the circulating influenza strains than last year's vaccine. Only 1 of the 3 strains of influenza virus contained in last year's vaccine proved to be effective. This year's vaccine contains 3 new strains of influenza, 2 influenza A strains and 1 influenza B strain. Another change from past years is the recommendations on who gets vaccinated. The CDC is currently recommending vaccination for all children 6 months to 18 years, adults over 50 years, patients with chronic diseases, pregnant women, and those individuals that are likely to be in contact with patients who have the flu. The CDC is hoping to



decrease the incidence of the flu in the school system, as this represents a high percentage of influenza cases each year. Officials are certain the supply of vaccines will be adequate to cover the increased number of individuals being recommended for vaccination.

Reinberg S. Flu vaccine should be more effective: CDC. Washington Post. 2008 Sep 24.

<http://www.washingtonpost.com/wp-dyn/content/article/2008/09/24/AR2008092402080.html>

Increased risk of death with Eprex ... Eprex (epoetin alpha), an erythropoiesis-stimulating agent typically used for anemia, was associated with an increased risk of death in a recent German study of stroke patients. In the study 16% of the participants who received the study drug died, compared to 9% in the placebo group. The drug was being tested to see if it could improve brain function in patients who had suffered a stroke. The manufacturer of Eprex, Johnson & Johnson, reported they would conduct further analysis. The safety of erythropoiesis-stimulating agents has been questioned due to the occurrence of tumor growth and decreased survival in patients receiving high doses. These findings suggest the need for increased monitoring of these agents and further testing to ensure their safety.

Reuters. FDA reviewing deaths in anemia drug study. New York Times. 2008 Sep 26; p. A19.

<http://www.nytimes.com/2008/09/27/health/27drug.html>

Medicare to stop paying for other's errors ... Beginning October 1, Medicare stopped paying hospitals for added costs associated with errors occurring under their care. Initially, 10 items are deemed to be preventable errors for which Medicare will not pay. These include complications related to incompatible blood transfusions, development of infection after certain surgeries, second operation to retrieve a sponge left behind from the first, serious bed sores, injuries from falls and urinary tract infections caused by catheters. This policy will also prevent the hospital from billing the patient directly for those costs accrued due to errors. Other private and public insurers plan to implement similar policies. This plan estimates Medicare's savings to be approximately \$21 million per year, which does not amount to substantial savings considering they spent \$110 billion dollars on inpatient care last year. The most obvious benefit of this policy would be a trend toward improved safety and reduction of preventable medical errors.



Sack K. Medicare won't pay for medical errors. New York Times. 2008 Sep 30; p. A1.

<http://www.nytimes.com/2008/10/01/us/01mistakes.html?pagewanted=1&ref=health>



The last "dose" ...

If we got one-tenth of what was promised to us in these acceptance speeches there wouldn't be any inducement to go to heaven.

~Will Rogers [1879 - 1935], American Humorist



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>

Bernie R. Olin, Pharm.D., Director