



## Key Inforbits

- 2 new drugs approved
- Pharmacists and drug interaction identification
- Health report – good and bad for Alabama
- Airborne takes a nose dive ...
- Methadone in the news, for good and bad
- Football season is coming ...

## NEW DRUGS, and other related stuff ...

**New Drug** ... (8/1/2008) **Clevidipine butyrate (Cleviprex™ by the Medicines Co)** is a dihydropyridine calcium channel blocker indicated for blood pressure reduction when oral therapy is not feasible or desirable; it is intended for intravenous use. Clevidipine is contraindicated in patients with allergies to soybeans, soy products, eggs, or egg products; defective lipid metabolism such as pathologic hyperlipemia, lipoid nephrosis, or acute pancreatitis if it is accompanied by hyperlipidemia; and in patients with severe aortic stenosis. Hypotension and reflex tachycardia are potential consequences of rapid upward titration. Discontinue the drug or titrate downward while oral therapy is established. Dihydropyridine calcium channel blockers produce negative inotropic effects and can exacerbate heart failure. Common adverse reactions (> 2%) are headache, nausea, and vomiting. Maintain aseptic technique with the product; it contains phospholipids and can support microbial growth. Do not use if contamination is suspected. Once the stopper is punctured, use within 4 hours.

<http://www.cleviprex.com/default.cfm> (Manufacturer web site including package insert)

**New Drug** ... (8/15/2008) The FDA has approved **tetrabenazine (Xenazine™ by Prestwick Pharmaceuticals, Inc.)** for treatment of chorea in people with Huntington's disease. Huntington's disease is a rare, inherited neurological disorder affecting about 1 in 10,000 people in the US. Symptoms commonly develop between ages 30 and 50; the patient may live for another 15-20 years after the onset of symptoms. Chorea is the jerky, involuntary movement that occurs in people with this disease. Xenazine™ is the first treatment approved in the US for any symptom of Huntington's disease. Serious side effects include depression and suicidal thoughts and actions. Concerns about the risk of suicide are heightened in all patients with Huntington's disease. The most common side effects reported in clinical trials include insomnia, depression, drowsiness, restlessness and nausea.

Xenazine™ was granted orphan drug designation by the FDA.

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01874.html>

**New Indication** ... (8/11/2008) The FDA has approved the HIV drug **tenofovir disoproxil fumarate (Viread® by Gilead Sciences) for chronic hepatitis B (HBV) in adults**. The recommended dose for the treatment of chronic HBV is 300 mg once daily taken orally without regard to food. The drug, however, should only be used as part of an appropriate antiretroviral combination regimen in HIV-infected patients with or without HBV co-infection.

[http://www.gilead.com/pr\\_1186292](http://www.gilead.com/pr_1186292) (Manufacturer web site)

**Labeling Changes ... Erythropoiesis-stimulating Agents (ESAs) ...** (7/30/2008) On April 22, 2008, the FDA notified the manufacturer of Epogen/Procrit (epoetin alfa) and Aranesp (darbepoetin alfa) of its decision to require additional safety-related changes to the labeling for these products. Amgen submitted labeling supplements for Epogen/Procrit and Aranesp on May 22, 2008, following the March 13, 2008 Oncologic Advisory Committee's recommendations to make additional safety-related changes to the labeling for these products. Amgen and the FDA have agreed on many of these changes, including to replace the existing Patient Package Insert with a Medication Guide and to modify certain sections of the Boxed Warnings, Indications and Usage, and Dosage and Administration sections of the package insert. These changes clarify the FDA-approved conditions for use of ESAs in patients with cancer and revise directions for dosing to state the hemoglobin level at which treatment with an ESA should not be initiated. Amgen and the FDA have not reached agreement on specific wording on two points, including a warning statement that ESAs are not intended for use in patients receiving myelosuppressive therapy when the expected outcome is cure and statements regarding when to initiate and to discontinue ESA therapy. The FDA urges healthcare professionals to promptly report serious and unexpected adverse reactions associated with Epogen, Procrit and Aranesp to the FDA MedWatch reporting program. A history of this action in several documents are available at: <http://www.fda.gov/cder/drug/infopage/RHE/default.htm>

**MedWatch ...** (8/8/2008) The FDA notified healthcare professionals of the **risk of muscle injury and rhabdomyolysis, which can lead to kidney failure or death, when simvastatin is used with amiodarone**. This risk is dose-related and increases when a dose of simvastatin greater than 20 mg per day is given with amiodarone. Although a revision of the simvastatin labeling in 2002 described this increased risk, the FDA continues to receive reports of rhabdomyolysis in patients treated concurrently with amiodarone and simvastatin. Read the complete MedWatch safety summary, including links to the FDA Drug Information page, Information for Healthcare Professionals sheet, and labels (Prescribing Information) for simvastatin and amiodarone products, at <http://www.fda.gov/medwatch/safety/2008/safety08.htm#Simvastatin>

**MedWatch ...** (8/12/2008) The FDA informed healthcare professionals of the risk of **adverse injection site reactions in patients receiving naltrexone**; it is indicated for the treatment of alcohol dependence in patients who are able to abstain from alcohol in an outpatient setting prior to initiation of treatment. Naltrexone is administered as an intramuscular gluteal injection and should not be administered intravenously, subcutaneously, or inadvertently into fatty tissue. Patients should monitor the injection site and contact their physician if they develop pain, swelling, tenderness, induration, bruising, pruritus, or redness at the injection site that does not improve or worsens within two weeks. Physicians should promptly refer patients with worsening injection site reactions to a surgeon. Read the FDA recommendations for healthcare professionals to consider regarding the use of naltrexone injection. Read the entire MedWatch Safety Summary, including a link to the FDA Drug Information Page regarding this issue at: <http://www.fda.gov/medwatch/safety/2008/safety08.htm#naltrexone>

## **FROM THE MEDICAL LITERATURE ...**

**Pharmacists rank high as identifier of drug interactions ...** A recent study conducted a survey of 12,500 prescribers (mostly physicians) with 950 usable responses. The survey was to

intended to gather information concerning prescribers knowledge of drug-drug interactions, based on 14 drug interaction pairs and to determine their source of information about drug interactions. Prescribers correctly identified drug interactions and their severity about 43% of the time (range 18.2% - 81.2%). Sources of information included personal digital assistants (PDA, ~25%) and paper sources (~25%). Strikingly, about 68% said they relied on pharmacists to inform them about potential drug interactions, presumably at the point of dispensing. Vigilance is a professional obligation!

Ko Y, Malone DC, Skrepnek GH, Armstrong EP, Murphy JE, et al. Prescribers' knowledge of and sources of information for potential drug-drug interactions: A postal survey of US prescribers. *Drug Safety*. 2008;31:525-536.



**Are we healthy?** ... The Behavioral Risk Factor Surveillance System (BRFSS) is an ongoing, state-based, random-digit-dialed telephone survey of the noninstitutionalized U.S. population aged >18 years. BRFSS collects data on health-risk behaviors and use of preventive health services related to the leading causes of death and disability in the United States.



This report presents results for 2006 for all 50 states, DC, Puerto Rico, the U.S. Virgin Islands, 145 selected metropolitan and micropolitan statistical areas (MMSAs), and 234 corresponding counties. Local and state health departments and federal agencies use BRFSS data to measure progress toward achieving national and local health objectives such as Healthy People 2010. Measurements included prevalence rates of fair or poor health; health-care; teeth extraction among adults aged >65 years; activity limitation as a result of physical, mental, or emotional problems; adults who had a recent routine checkup; annual influenza vaccination among adults aged >65 years; pneumococcal vaccination among older adults; sigmoidoscopy/colonoscopy among adults aged >50 years; adults aged >50 years who had a blood stool test during the preceding 2 years; women having a Papanicolaou (Pap) test during the preceding 3 years; women aged >40 years having a mammogram during the preceding 2 years; men aged >40 years who had a prostate-specific antigen (PSA) test during the preceding 2 years; cigarette smoking; binge drinking; leisure-time physical inactivity; use of seat belts; adults who were overweight and obese; current asthma prevalence; diabetes; coronary heart disease among adults aged >45 years; stroke history among adults aged >45 years. **Alabama** did reasonably well in some categories, not so well in others; see linked document.

Kilmer G, Roberts H, Hughes E, Li Y, Valluru B, Fan A, Giles W, Mokdad A, Jiles R. Surveillance of certain health behaviors and conditions among states and selected local areas – Behavioral risk factor surveillance system (BRFSS), United States, 2006. *MMWR*. 2008 Aug 15;57(SS-7):1-192.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/ss5707a1.htm>

### Reviews of Note ...

- Hesketh PJ. Chemotherapy-induced nausea and vomiting. *N Engl J Med*. 2008 Jun 5;358(23):2482-2494.
- Cernik C, Galina K, Brodell RT. The treatment of herpes simplex infections: An evidence-based review. *Arch Intern Med*. 2008 Jun 9;168(11):1137-1144.
- Gray CL, Ndefo UA. Nebivolol: A new antihypertensive agent. *Am J Health-Syst Pharm*. 2008 Jun 15;65:1125-1133.
- Sullivan J, Amarshi N. Dual antiplatelet therapy with clopidogrel and aspirin. *Am J Health-Syst Pharm*. 2008 Jun 15;65:1134-1143.
- De Rijdt T, Willems L, Simoens S. Economic effects of clinical pharmacy interventions: A literature review. *Am J Health-Syst Pharm*. 2008 Jun 15;65:1161-1172.
- Brent GA. Graves' disease. *N Engl J Med*. 2008 Jun 12;358(24):2594-2605.

## **FROM THE LAY LITERATURE about medicine ...**

**Airborne takes a nose dive ...** Airborne is a ‘natural product’ containing a formulation of vitamins, minerals and some herbs and promoted to cure or prevent colds, at least until that claim was challenged and the product company was sued for deceptive advertising by the Federal Trade Commission, Bureau of Consumer Protection.



The product was created in 1997 by Victoria Knight-McDowell, a second grade teacher tired of catching all manner of viruses from her students. That proved to be marketing nirvana and the product has sold well (>\$100 million per year). Many have recognized the possibility/probability of a placebo effect, but continue to believe in the product.

Shin A. Airborne coughs up millions to settle suit. Washington Post. 2008 Aug 15; p. D1.

<http://www.washingtonpost.com/wp-dyn/content/article/2008/08/14/AR2008081403142.html?wpisrc=newsletter>

**Methadone – A mixed blessing ...** Methadone has been available for many years, but has been primarily used as a maintenance/weaning drug for heroin abusers. It has been increasingly used for pain relief but, also increasingly used by opiate abusers. This combination has dramatically increased the deaths associated with the drug. Methadone has a very long duration of action and many physicians do not know how to prescribe it appropriately. Because proper use must take into account the pharmacokinetics of the drug, previous opiate use, patient factors, drug interactions, etc. the FDA/DEA are considering requiring special training for physicians to prescribe it. While this may or may not happen, it behooves pharmacists to be familiar with methadone’s intricacies and consult with physicians who may not be a familiar with the drug as they need to be.

Eckholm E, Pierce O. Methadone rises as a painkiller with big risks. New York Times. 2008 Aug 17.

<http://www.nytimes.com/2008/08/17/us/17methadone.html?ref=health>

## **AUBURN HSOP FACULTY and STUDENTS in the literature ...**

- Chung AM, Eiland LS. Use of second-generation antiepileptic drugs in the pediatric population. *Pediatric Drugs*. 2008;10(4):217-254.
- Woodis CB. Once-yearly administered intravenous zoledronic acid for postmenopausal osteoporosis. *Ann Pharmacother*. 2008 Jul/Aug;42(7/8):1085-1089.



### **The last “dose” ...**

“When I played pro football, I never set out to hurt anyone deliberately – unless it was, you know, important, like a league game or something.”

~Dick Butkus, former professional football player, linebacker (#51) Chicago Bears, actor [1942 - ]

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