

AU InforMed

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Key Inforbits

- Vaccines work!
- Minnesota is inhospitable
- Make old meds yucky
- November is Diabetes Awareness month
- Beware of the Power Vampire
- Happy Thanksgiving!

NEW DRUGS, and other related stuff ...

New Drug ... (11/14/2007) The FDA has approved **methoxy polyethylene glycol-epoetin beta (Mircera[®] by Roche)** for the treatment of anemia associated with chronic renal failure (CRF) in adults, including patients on dialysis and patients not on dialysis. Mircera[®] is the only FDA-approved erythropoiesis-stimulating agent (ESA) to provide correction of anemia with once-every-two-week dosing. Mircera[®] is also the only FDA-approved ESA to maintain stable hemoglobin levels with once-monthly or once-every-two-week dosing in CKD patients. It offers the added convenience of room temperature storage for extended time periods when necessary. The outcome of an ongoing patent case will determine when patients can gain access to Mircera[®] in the U.S. Following approval by the European Agency for the Evaluation of Medicinal Products (EMA), the product has already been launched in Austria, Sweden, Germany, the United Kingdom and Norway, and will continue its international rollout.

<http://www.rocheusa.com/newsroom/current/2007/pr2007111401.html> [Manufacturer web site]

Label Changes ... (11/8/2007) The FDA has approved revised boxed warnings and other safety-related product labeling changes for **erythropoiesis-stimulating agents (ESAs)**, which treat certain types of anemia. These new statements address the risks that the drugs Aranesp, Epogen and Procrit pose to patients with cancer and patients with chronic kidney failure. The labeling changes, which incorporate advice from FDA advisory committees and expand upon labeling changes made in March 2007, also include a statement that symptoms of anemia, fatigue and quality of life have not been shown to improve in patients with cancer who are treated with ESAs. Epogen, Procrit and Aranesp are approved to treat anemia in patients with chronic kidney failure and anemia caused by chemotherapy in certain patients with cancer. Epogen and Procrit are also approved for use in certain patients with anemia who are scheduled to undergo major surgery to reduce blood transfusions during or shortly after surgery and for the treatment of anemia caused by zidovudine (AZT) therapy in HIV patients.

For more information: <http://www.fda.gov/cder/drug/infopage/RHE/default.htm> or <http://www.fda.gov/bbs/topics/NEWS/2007/NEW01740.html>

MedWatch ... (11/5/2007) The FDA announced that, at the agency's request, Bayer Pharmaceuticals Corp. has agreed to a **marketing suspension of Trasylol (aprotinin injection)**, a drug used to control bleeding during heart surgery, pending detailed review of preliminary results from a Canadian study that suggested an increased risk for death. FDA has not yet received all study data but expects to act quickly with Bayer, the study's researchers at the

Ottawa Health Research Institute, and other agencies to undertake a thorough analysis of data. However, FDA is committed to continued, limited access to Trasylol for specific situations. Read the complete MedWatch 2007 Safety Summary including a link to the "FDA News" and Drug Information Page, at: <http://www.fda.gov/medwatch/safety/2007/safety07.htm#Trasylol>

MedWatch ... (11/14/2007) The FDA issued an early communication about the ongoing review of new safety data and the request for additional data to further evaluate the **risk of death in patients treated with cefepime**. An article in the May 2007 issue of *The Lancet Infectious Diseases* (Efficacy and safety of cefepime: a systematic review and meta-analysis) raised the question about increased mortality with the use of cefepime, a broad spectrum β -lactam antibiotic. The article describes a higher all-cause mortality in patients treated with cefepime compared to other β -lactam antibiotics. Until FDA's evaluation is completed, healthcare professionals should be aware of the risks and benefits described in the prescribing information and the new information from this meta-analysis.

Read the complete MedWatch 2007 Safety Summary including a link to the Early Communication Sheet regarding this ongoing safety review at: <http://www.fda.gov/medwatch/safety/2007/safety07.htm#Cefepime>

MedWatch ... (11/14/2007) The FDA announced new information added to the existing **boxed warning in Avandia[®]'s prescribing information about potential increased risk for heart attacks**. The new information refers to a meta-analysis of 42 clinical studies, most of which compared Avandia[®] to placebo, that showed Avandia[®] to be associated with an increased risk of myocardial ischemic events such as angina or myocardial infarction. FDA has concluded that there isn't enough evidence to indicate that the risks of heart attacks or death are different between Avandia[®] and some other oral type 2 diabetes treatments. People with type 2 diabetes who have underlying heart disease or who are at high risk of heart attack should talk to their healthcare professional. Healthcare professionals are advised to closely monitor patients who take Avandia[®] for cardiovascular risks.

Read the complete MedWatch 2007 Safety Summary including a link to the FDA News Release regarding this issue at: <http://www.fda.gov/medwatch/safety/2007/safety07.htm#Avandia2>

FROM THE MEDICAL LITERATURE ...

It works ... A retrospective review was conducted using historical data and reports from the national passive surveillance system for applicable diseases, to determine effectiveness of vaccines on preventing their respective illnesses. Outcome measures included number of cases, deaths and hospitalizations for 13 vaccine-preventable diseases: Diphtheria, measles, mumps, pertussis, poliomyelitis, rubella, smallpox, tetanus, hepatitis A, hepatitis B, *Haemophilus influenzae type b*, invasive pneumococcal disease, and varicella. Some results included a >92% decline in cases and \geq 99% decrease in deaths for diphtheria, mumps, pertussis and tetanus. Endemic transmission of polio, measles and rubella have been virtually eliminated in the U.S. and smallpox eradicated worldwide. Declines were not as great for some of the newer vaccines (eg, hepatitis A,B, *H. flu*, varicella), but still about 80% reduction in cases and deaths; if the pattern follows these will also show continued decreases in coming years.

Roush SW, Murphy TV, and the Vaccine-Preventable Disease Table Working Group. Historical comparisons of morbidity and mortality for vaccine-preventable diseases in the United States. *JAMA*. 2007 Nov 14;298:2155-2163.

Reviews of Note ...

- Valeyrie-Allanore L, Sassolas B, Roujeau J-C. Drug-induced skin, nail and hair disorders. *Drug Safety*. 2007;30(11):1011-1030.
- Ganesh A, Maxwell LG. Pathophysiology and management of opioid-induced pruritus. *Drugs*. 2007;67(16):2323-2333.
- Frampton JE, Keating GM. Celecoxib: A review of its use in the management of arthritis and acute pain. *Drugs*. 2007;67(16):2433-2472.

FROM THE LAY LITERATURE about medicine ...

Limits on physician entreaties ... In Minnesota, its cold in more ways than one. It is one of the few states that have put severe restrictions on gifts to physicians from pharmaceutical companies; limits are \$50 per year, including food, etc. In addition, there are requirements for public reporting of all such gifts. This has put a severe damper on some restaurants that provided such meals (usually lunches for the office staff), but it has also decreased visits by pharmaceutical representatives to physician offices (no treats, no time). One ploy being used is hiring physicians as expert speakers, usually done at nice restaurants, and the audience is nurses and administrative staff of physician offices. We can only presume how that works out. Several other states, and the U.S. Congress are considering similar measures.

Harris G. Minnesota limit on gifts to doctors may catch on. *New York Times*. 2007 Oct 12.

<http://www.nytimes.com/2007/10/12/us/12gift.html?ref=health>

Don't just toss those old meds ... make them yucky ... A new twist on the old advice to discard unused medicines. A test campaign by the Substance Abuse and Mental Health Services Administration (SAMHSA) is underway to encourage patients to discard their medicines, but to also render them unusable by mixing them with used kitty litter, dog droppings, saw dust or coffee grounds, sealing them in a plastic bag and tossing it in the trash. The primary aim is to curb prescription drug abuse; a big chunk comes from our medicine cabinets. The old advice of flushing down the toilet is no longer advocated due to contamination of the water supply. Leakage from landfills at least takes longer.



Associated Press. Don't toss old meds – make them yucky. *CNN.com* 2007 Nov 6.

<http://www.cnn.com/2007/HEALTH/11/05/tossing.drugs.ap/index.html>

AUBURN HSOP FACULTY and STUDENTS in the literature ...

- DeRuiter J, Holston PL, DeRuiter AP. New drug review. *US Pharm*. 2007 Oct;32(10):26, 29, 30, 33, 34, 36, 38.
- Bell EC, Ravis WR, Chan HM, Lin Y-J. Lack of pharmacokinetic interaction between St. John's Wort and prednisone. *Ann Pharmacother*. 2007 Nov;41:1819-1824.

Update ...

National Diabetes Awareness Month, November 2007 ... In 2005, approximately 21 million persons in the U.S. had diabetes and in 2002, at least 54 million U.S. adults had prediabetes. Lifestyle changes, such as moderate weight loss and increased physical activity, can prevent or delay onset of type 2 diabetes among adults at high risk, and effective interventions are available to reduce the incidence of diabetes complications. Also, World Diabetes Day (WDD) is November 14, and this year marks the first observance of WDD by the United Nations.

Information on diabetes prevention and control is available from CDC at <http://www.cdc.gov/diabetes> and from the National Diabetes Education Program at <http://www.ndep.nih.gov>. Information on WDD activities is available at <http://www.worlddiabetesday.org>.
<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5643a1.htm>

NEW RESOURCES in the DILRC ...

- Cooper DH, Krainik AJ, Lubner SJ, Reno HEL, eds. *The Washington Manual of Medical Therapeutics*. 32nd ed. Baltimore: Lippincott Williams & Wilkins/Wolters Kluwer Health. 2007.
- *PDR for Herbal Medicines*. 4th ed. Montvale, NJ: Thomson Healthcare Inc, 2007.
- Schaefer C, Peters P, Miller RK, eds. *Drugs During Pregnancy and Lactation*. 2nd ed. Amsterdam: Elsevier/Academic Press, 2007.
- Aronoff GR, Bennett WM, Berns JS, Brier ME, Kasbekar N, Mueller BA, Pasko DA, Smoyer WE. *Drug Prescribing in Renal Failure: Dosing Guidelines for Adults and Children*. 5th ed. Philadelphia: American College of Physicians, 2007.

TIMELY TOP TECH TIP ...

Power vampire is lurking ... Nearly all of us have been bitten. Its “vampire electronics,” those cellphone chargers that stay plugged in all night, all of those machines in “power saver mode,” all of those electronic devices that have a digital clock, toothbrushes and power tools that are on constant charge, not to mention computers and peripherals. It is estimated that these tiny little energy users account for 5% of all the electricity used in the U.S. This equates to about \$4 billion a year and the percentage could rise to 20% by 2010. A government-backed program, Energy Star, has been established to address the problem. They estimate that if only 10% of American homes endorsed their program and killed the vampire, it would reduce carbon emissions equivalent to planting 1.7 million acres of trees.



Associated Press. New kind of ‘vampire’ sucks power out of homes. *CNN.com* 2007 Oct 30.

<http://www.cnn.com/2007/TECH/10/30/vampire.electronics.ap/index.html>



The last “dose” ...



There is one day that is ours. There is one day when all we Americans who are not self-made go back to the old home to eat saleratus biscuits and marvel how much nearer to the porch the old pump looks than it used to. Thanksgiving Day is the one day that is purely American.
~William Sydney Porter (a.k.a., O. Henry) [1862 - 1910]



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