

AU InforMed

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Key Inforbits

- Expensive placebos work better
- STDs more common in teenagers than thought
- Brain pumping need an asterisk?
- Drugs in the water, oh my!
- World Kidney Day, March 13th
- The purpose of medicine ...?

NEW DRUGS, and other related stuff ...

Expanded Indication ... (2/28/2008) The FDA approved **Nexium (esomeprazole magnesium, a proton pump inhibitor, by AstraZeneca) for short-term use in children ages 1-11 years for the treatment of gastroesophageal reflux disease (GERD)**. The agency approved Nexium in two forms, a delayed-release capsule and liquid form. Nexium is approved in 10 mg or 20 mg daily for children 1-11 years old compared to 20 mg or 40 mg recommended for pediatric patients 12 to 17 years of age. The most common adverse reactions in children treated with Nexium were headache, diarrhea, abdominal pain, nausea, gas, constipation, dry mouth and sleepiness. <http://www.fda.gov/bbs/topics/NEWS/2008/NEW01802.html>

Rosiglitazone Medication Guide ... (2/26/2008) FDA and GlaxoSmithKline notified pharmacists and physicians of a new **Medication Guide for Avandia (rosiglitazone maleate)**. The FDA regulation 21CFR 208 requires a Medication Guide to be provided with each prescription that is dispensed for products that the FDA determines pose a serious and significant public health concern. A list of currently approved Medication Guides are available at http://www.fda.gov/cder/Offices/ODS/medication_guides.htm. See the MedWatch 2008 safety summary, including links to the Medication Guide and the current Prescribing Information for Avandia, at: <http://www.fda.gov/medwatch/safety/2008/safety08.htm#Avandia>

MedWatch ... (2/26/2008) FDA announced the risk of **serious allergic reactions in users of denture cleansers**. These adverse events, including abdominal pain, vomiting, seizures, hypotension and difficulty breathing, have occurred both when the product has been used properly as well as from improper use. These events can occur soon after first use or after years of use. FDA believes that the ingredient responsible for these reactions is persulfate, a known allergen. Persulfates are used in most denture cleansers to help clean and bleach the dentures. FDA has provided specific recommendations for dental healthcare professionals and an 'Advice for Patients' document. See the MedWatch 2008 safety summary, including links to the Public Health Notification and "Advice for Patients", at: <http://www.fda.gov/medwatch/safety/2008/safety08.htm#Denture>

MedWatch ... (3/4/2008) Palo Alto Labs and FDA notified consumers and healthcare professionals of a **voluntary nationwide recall** of two dietary supplements, Aspire36 and Aspire

Lite. The products were recalled because they were found to contain Aildenafil in trace amounts and Dimethyl sildenafil thione, an analog of Sildenafil, a drug used to treat erectile dysfunction. The presence of these ingredients in the dietary supplements may pose a threat to consumers because the analogue may interact with nitrates (such as nitroglycerin) and may lower blood pressure to dangerous levels. Consumers who have Aspire36 and Aspire Lite in their possession should stop using the products and return any unused product to the place of purchase.

Read the complete 2008 MedWatch Safety Summary, including a link to the manufacturer's press release regarding this issue at:

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

MedWatch ... (3/11/2008) The FDA informed healthcare professionals of life-threatening adverse events and death in patients, including children, who have received Tussionex Pennkinetic Extended-Release Suspension (Tussionex). Healthcare professionals have prescribed Tussionex for patients <6 years old, and more frequently than the labeled dosing interval of every 12 hours. Tussionex is contraindicated for use in patients <6 years of age because of their susceptibility to life-threatening and fatal respiratory depression. Patients have administered the incorrect dose due to misinterpretation of the dosing directions, and have used inappropriate devices to measure the suspension. Overdose of Tussionex in older children, adolescents, and adults has also been associated with life-threatening and fatal respiratory depression. A properly marked measuring device should be used to measure Tussionex to prevent overdose.

Read the complete 2008 MedWatch Safety Summary, including links to the Public Health Advisory, Information for Healthcare Professionals, and the Prescribing Information at:

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

FROM THE MEDICAL LITERATURE ...

Counseling patients on dietary supplements ... Here is an article intended for a physician audience, but lays out an approach to patient counseling about dietary supplements. It is a



common sense approach and covers the basics – it even provides a list of recommended references, most of which are reasonable. Many of us have been preaching this approach for years, but sometimes it has more impact when seen in print. The major points include asking the patient about supplement use; evaluating the supplement; discussing regulatory issues (or lack thereof); discussing safety/efficacy and risk/benefit; monitoring for adverse events (including drug/herb interactions) and response.

Ashar BH, Rowland-Seymour A. Advising patients who use dietary supplements. *Am J Med.* 2008 Feb;121(2):91-7.

Expensive placebos are more effective ... In a small study of 86 volunteers, electric shocks



were administered to test the effectiveness of two analgesic placebos. The only difference was that one placebo was presented as costing \$2.50 and the other priced at \$0.10. The more expensive placebo was considerably more effective (85.4% vs. 61%). The authors suggest that this explains a lot concerning the popularity of new and very expensive therapies even when much cheaper, and probably equally effective alternatives exist (eg, NSAIDs). Go figure.



Waber RL, Shiv B, Carmon Z, Ariely D. Commercial features of placebo and therapeutic efficacy. *JAMA.* 2008 Mar 5;299(9):1016-1017.

STDs more prevalent than thought ... in a press release from the Centers for Disease Control and Prevention (CDC), a newly completed study was described that indicated 26% of teenage girls (ages 14-19 years), roughly 3.2 million, have a sexually transmitted disease (STD). Most

commonly these are human papillomavirus (HPV), chlamydia, herpes simplex virus and trichomoniasis. By ethnicity, approximately 48% of African-American female teenagers were infected and 20% of white females. HPV was most common at 18%. The study was based on data gathered in a 2003-2004 survey.

<http://www.cdc.gov/stdconference/2008/media/release-11march2008.htm>

Reviews of Note ...

- Mizgerd JP. Acute lower respiratory tract infection. *N Engl J Med*. 2008 Feb 14;358(7):716-727.
- Acheson AG, Scholefield JH. Management of haemorrhoids. *BMJ*. 2008 Feb 16;336:380-383.
- McCabe SM, Ma Q, Slish JC, Catanzaro LM, Sheth N, DiCenzo R, Morse G. Antiretroviral therapy: Pharmacokinetic considerations in patients with renal or hepatic impairment. *Clin Pharmacokinet*. 2008;47(3):153-172.
- Bennett CL, Silver SM, Djulbegovic B, Samaras AT, Blau CA, Gleason KJ, et al. Venous thromboembolism and mortality associated with recombinant erythropoietin and darbepoetin administration for the treatment of cancer-associated anemia. *JAMA*. 2008 Feb 27;299(8):914-924.
- Doty RL, Shah M, Bromley SM. Drug-induced taste disorders. *Drug Safety*. 2008;31(3):199-215.

FROM THE LAY LITERATURE about medicine ...

Actor, Doctor, or dealer's choice ... An essay by a physician that takes a couple of pages to tell us what we already know, that advertisements for drugs are just that, advertisements; and we are all vulnerable to its messages. It doesn't matter whether it's an unlicensed physician, actor or body double (as in the recent case of Dr. Jarvik as spokesman for Lipitor®). She takes the opportunity to say, "Perhaps it is the time for all drug advertising to be reformulated according to the premise that a medication is too powerful, serious and subtle a commodity to be promoted by attractive or famous individuals – doctors or actors – making implicit or explicit promises while indulging in vigorous exercise and pocketing checks." Zuger A. Drug pitchmen: Actor, doctor or Pfizer's option. *New York Times*. 2008 Mar 4.



http://www.nytimes.com/2008/03/04/health/views/04essa.html?_r=1&ref=health&oref=slogin

Nobel laureate* but ... Are we heading for a time when academic achievement may be "sanctioned" as some sports figures may be, officially or unofficially with an asterisk by the record or achievement? Much attention has been paid to the "doping of sports" particularly with anabolic steroids producing virtual super-athletes from high school up to the professional ranks. A more recent debate is percolating regarding brain pumping. Applying the same arguments from sports, is it bad to chemically enhance the brain via use of stimulants to increase attention span and wakefulness? Is it cheating to use stimulants to study longer or do better on an exam? If someone learns more, thinks more, and perhaps develops a new drug or process that ultimately helps others, due to taking a drug outside of intended indications, is it detrimental? To whom? Short term, long term? Thought provoking, to say the least.



Carey B. Brain enhancement is wrong, right? *New York Times*. 2008 Mar 9.

http://www.nytimes.com/2008/03/09/weekinreview/09carey.html?_r=1&ref=health&oref=slogin

Drugs in the water ... This alarm has been sounding for several years, but a recent study by the Associated Press (and thus picked up by virtually every newspaper and television station) has shown that, depending on location, many drug compounds can be found in our drinking water. The amounts are very miniscule, but the point is made that we have no idea what the long term effects may be after decades of such exposure. Bottled water and water put through home filtration devices may not be any better. The primary source of this contamination is human and animal waste; that is we take a drug and excrete some portion of it that goes directly into the waste treatment process. It's an interesting report, but with few conclusions and devoid of recommendations, other than we should pay attention.



Donn J, Mendoza M, Pritchard J. AP probe finds drugs in the drinking water.
http://news.yahoo.com/s/ap/20080309/ap_on_re_us/pharmawater_i

AUBURN HSOP FACULTY and STUDENTS in the literature ...

- Edwards JD, Eiland III EH. Statins for the treatment of sepsis. US Pharm. 2008 Feb;33(2):HS-3, HS-6, HS-8, HS-15.
- Fox BI, Felkey BG. Pharmacists, get connected: Cellular broadband for smartphones. Hosp Pharm. 2008 Mar;43:227-230.

Update ...

World Kidney Day, March 13, 2008 ... is to raise awareness of kidney disease and educate persons at risk about the importance of prevention and early detection. Kidney disease, the ninth leading cause of death in the United States, is a costly disease associated with severe morbidity and premature death. Information about kidney disease prevention and control is available from the National Kidney Disease Education Program at <http://www.nkdep.nih.gov>. Information on World Kidney Day activities is available at <http://www.worldkidneyday.org>.



Notice to readers: World kidney day, March 13, 2008. MMWR. Feb 29;57(8):207.
<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5708a5.htm>



The last "dose" ...

"The original purpose of medicine is to heal the sick, not turn healthy people into gods."

--Francis Fukuyama [1952 -], from "Our Posthuman future: Consequences of the Biotechnology Revolution" Macmillan, 2003

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