

AU InforMed

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Key Inforbits

- Many, many MedWatches
- New guidelines for lung cancer
- Practical problems with patches
- Suffering not limited to hunger in 3rd world
- Senate may be addressing Big Pharma largess
- International tips on healthy eating

NEW DRUGS, and other related stuff ...

New Indication/Product ... Totect™ (dexrazoxane for injection by Integrated Commercialization Solutions [distributor]; Ben Venue Labs [manufacturer]; TopoTarget A/S [parent]) has been approved for treatment of extravasation resulting from IV anthracycline chemotherapy. Dexrazoxane is a cytotoxic drug and is rated as Pregnancy Category D. Totect™ (dexrazoxane) for injection. Package Labeling. Copenhagen, Denmark: TopoTarget A/S. September 2007.

New Generic ... (9/5/2007) The FDA has approved the first generic versions of **Coreg® (carvedilol)**. It is widely used to treat high blood pressure, mild to severe chronic heart failure and left ventricular dysfunction following a heart attack. Carvedilol tablets come in four strengths (3.125 mg, 6.25 mg, 12.5 mg and 25 mg). The following companies applications have been approved: Actavis Elizabeth LLC; Apotex Inc.; Aurobindo Pharma Limited; Caraco Pharmaceutical Laboratories Limited; Dr. Reddy's Laboratories; Glenmark Pharmaceuticals Limited; Lupin Limited; Mylan Pharmaceuticals Inc.; Ranbaxy Laboratories Ltd.; Sandoz Inc.; Taro Pharmaceutical Industries Ltd.; TEVA Pharmaceuticals USA; Watson Laboratories Inc.; and Zydus Pharmaceuticals USA Inc. The labeling of the generic products may differ from that of Coreg® because parts of the Coreg® labeling are protected by patents and/or exclusivity. For more information: FDA's Office of Generic Drugs www.fda.gov/cder/ogd/
FDA Approves First Generic Versions of Coreg. *FDA News*. 2007 Sep 5.
<http://www.fda.gov/bbs/topics/NEWS/2007/NEW01695.html>

MedWatch ... (9/7/2007) Bodee LLC, Inc., issued a **nationwide recall of Zencore Tabs**, a dietary supplement, because it contains the undeclared ingredients of aminotadalafil, an analog of tadalafil, and sildenafil, both of which are FDA-approved drugs used for Erectile Dysfunction. The product also contained sulfosildenafil and sulfohomosildenafil which are analogs of sildenafil. These products pose a threat to consumers because they may interact with nitrates (such as nitroglycerin) and may lower blood pressure to dangerous levels. Consumers who have this product should stop using it immediately and consult their healthcare professional if they experience any problems that may be due to this product.
Read the complete MedWatch 2007 Safety Summary including a link to the Firm's Press Release at: <http://www.fda.gov/medwatch/safety/2007/safety07.htm#Zencore>

MedWatch ... (9/10/2007) Pfizer issued a Dear Healthcare Professional Letter to inform of the presence of **ethyl methanesulfonate (EMS), a process-related impurity in Viracept®** and to

provide guidance on the use of Viracept® in pregnant women and pediatric patients. EMS is a potential human carcinogen and is teratogenic, mutagenic and carcinogenic in animals. FDA has asked Pfizer to limit the presence of EMS in Viracept® products marketed in the U.S. For pediatric patients who are stable on Viracept®-containing regimens, FDA and Pfizer agree that those patients may continue to receive Viracept®. Pediatric patients and pregnant women who need to begin HIV treatment should not start regimens containing Viracept® until further notice. As a precautionary measure, pregnant women currently receiving Viracept® should be switched to an alternative antiretroviral therapy. For pregnant women with no alternative treatment options, FDA and Pfizer agree that the risk-benefit ratio remains favorable for the continued use of Viracept®.

Read the complete MedWatch 2007 Safety summary, including a link to the Dear Healthcare Professional Letter and the FDA Drug Information Page, at:

<http://www.fda.gov/medwatch/safety/2007/safety07.htm#Viracept>

MedWatch ... (9/11/2007) Roche informed healthcare professionals about revisions made to the prescribing information for Rocephin® (ceftriaxone). **Rocephin® and calcium-containing solutions** including continuous calcium-containing infusions such as parenteral nutrition, should not be mixed or co-administered to any patient irrespective of age, even via different infusion lines at different sites. Rocephin® and IV calcium-containing solutions should not be administered within 48 hours of each other in any patient. No data are available on the potential interaction between ceftriaxone and oral calcium-containing products or interaction between intramuscular ceftriaxone and calcium-containing products (IV or oral).

Read the completed MedWatch 2007 Safety Summary including a link to the Dear Healthcare Professional Letter, Prescribing information, and the Healthcare Professional Sheet regarding this issue at: <http://www.fda.gov/medwatch/safety/2007/safety07.htm#Rocephin>

MedWatch ... (9/13/2007) Cephalon issued two Dear Healthcare Professional Letters to inform that Fentora® (fentanyl buccal) is indicated only for the management of breakthrough pain in patients with cancer who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. **Serious adverse events, including deaths, have occurred in patients treated with Fentora®.** These deaths occurred as a result of improper patient selection (e.g., use in opioid non-tolerant patients), improper dosing, and/or improper product substitution. Key points to reduce the risk of respiratory depression are provided.

Read the complete MedWatch 2007 Safety Summary including a link to the Dear Doctor and Dear Healthcare Professional Letters and Prescribing information, at:

<http://www.fda.gov/medwatch/safety/2007/safety07.htm#Fentora>

MedWatch ... (9/18/2007) Johnson and Johnson and the FDA informed healthcare professionals that the WARNINGS section of the prescribing information for haloperidol has been revised to include a new **Cardiovascular subsection regarding cases of sudden death, QT prolongation and Torsades de Pointes (TdP) in patients treated with haloperidol**, especially when given intravenously, or at doses higher than recommended. Although injectable haloperidol is only approved by the FDA for intramuscular injection, there is considerable evidence that the intravenous administration of haloperidol is a relatively common off-label clinical practice. There are at least 28 case reports of QT prolongation and TdP, some with fatal outcome in the context of off-label intravenous haloperidol. Healthcare professionals should consider this new risk information when making individual treatment decisions for their patients.

Read the complete MedWatch 2007 Safety Summary including a link to the Healthcare Professional Sheet at: <http://www.fda.gov/medwatch/safety/2007/safety07.htm#Haloperidol>

FROM THE MEDICAL LITERATURE ...

Guidelines ... Lung Cancer ... New guidelines have been issued from the American College of Chest Physicians for the diagnosis and management of lung cancer. It is a far-reaching guideline that includes 27 separate articles that encompass palliative care and complementary and alternative medicine. This doesn't mean herbal therapy is endorsed, but some dietary supplements are recommended in specific circumstances.



ACCP Evidence-based Clinical Practice Guidelines. 2nd ed. Diagnosis and management of lung cancer. *Chest*. 2007 Sep;132(3) Suppl:1S-422S. (27 articles)

Reviews of Note ...

- Lincoff AM, Wolski K, Nicholls SJ, Nissen SE. Pioglitazone and risk of cardiovascular events in patients with type 2 diabetes mellitus: A meta-analysis of randomized trials. *JAMA*. 2007 Sep 12;298(10):1180-1188.
- Singh S, Loke YK, Furberg CD. Long-term risk of cardiovascular events with rosiglitazone: A meta-analysis. *JAMA*. 2007 Sep 12;298(10):1189-1195.
- Green H, Paul M, Vidal L, Leibovici L. Prophylaxis of *Pneumocystis* pneumonia in immunocompromised non-HIV-infected patients: Systematic review and meta-analysis of randomized controlled trials. *Mayo Clin Proc*. 2007 Sep;82:1052-1059.

FROM THE LAY LITERATURE about medicine ...

Pain relief, sometimes not available at any price ... Did you know that six countries (U.S., Canada, France, Germany, Britain, Australia) consume 79% of the world's morphine? In poorer countries comprising 80% of the world's population, only 6% of the morphine supply is consumed. There is plenty of opium and morphine produced, and it is inexpensive. What is the problem? "Old" attitudes and beliefs about morphine and pain relief cause a great deal of fear about addiction and the danger of overdose. In some countries, the fear of beginning or increasing a drug trafficking problem prevents the importation of the drug for legitimate purposes altogether. Codeine and tramadol are often the best that can be provided.



McNeil DG Jr. Drugs banned, many of world's poor suffer in pain. *New York Times*. 2007 Sep 10.

<http://www.nytimes.com/2007/09/10/health/10pain.html?ref=health>

Free Gifts? The next step ... Legislation has been introduced in the U.S. Senate that would additionally regulate pharmaceutical companies and medical device makers concerning free gifts to physicians. If passed, it would require the companies to report quarterly the names of recipients, the value and dates of payments or gifts, purpose and exchange of value, if any. This would include continuing medical education, seminars, and payments to attend. This information would be posted on a public web site. The intent is for patients to be able to know if their physician is receiving payments from these companies. The companies complain that they are already over-regulated. This is a prime example of failure to self-regulate. Can other health professionals be far behind? Pharmacists? Mangan K. Senate bill would require drug companies to report all gifts to doctors. *Chronicle of Higher Education*. 2007 Sep 10.



<http://chronicle.com/daily/2007/09/2007091002n.htm> [subscription only]

5 nutritious habits ... and all non-drug related. From an author of *Cooking Light*, here are 5 nutritious habits, practiced in various countries around the world. There is no big secret here, but we can all use the reminder once in a while. The article at the web site below has much more information:

- Eat plenty of produce and whole grains
- Savor leisurely dining
- Practice portion control
- Eat a variety of unprocessed, fresh foods
- Spice up your plate



Huber L. 5 nutritious habits of the planet's healthiest countries. *CNN.com* 2007 Sep 12.

<http://www.cnn.com/2007/HEALTH/diet.fitness/08/31/cl.worldly.advice/index.html>

AUBURN HSOP FACULTY and STUDENTS in the literature ...

- Wargo KA, Geveden BN, McConnell VJ. Cannabinoid-induced pancreatitis: a case series. *J Pancreas*. 2007;8:579-83.

NEW RESOURCES in the DILRC ...

- Levin BL, Hurd PD, Hanson A. *Introduction to Public Health in Pharmacy*. Sudbury, MA: Jones and Bartlett, 2008.
- Netter FH, Bachrach WH. *Netter's Gastrointestinal Anatomy and Motility: Selections from the Netter Collection of Medical Illustrations*. NJ: Novartis, 2001.

TIMELY TOP TECH TIP ...

High tech, low touch ... An opinion piece by a medical resident debating the positive and negative aspects of the computerized medical record. While there is much benefit from having such a tool at the bedside (or clinic), such as improved access to previous information and improved accuracy, there is a downside. This resident found that he spent more time facing away from the patient and towards the computer screen. He opines that this may result in less patient interaction. While he concludes that the balance is favorable, the lesson is that as the electronic medical record comes more into play, as will other technologies, we must be careful that these tools don't become barriers between us and our patients.



Hochman M. My Perspective: Eyes shift from patient to keyboard. *Boston Globe*. 2007 Sep 10.

http://www.boston.com/yourlife/health/other/articles/2007/09/10/eyes_shift_from_patient_to_keyboard/



The last "dose" ...

"One day of practice is like one day of clean living. It doesn't do you any good."
--Abe Lemmons [1922 - 2002], former college basketball coach

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

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