

# AU InforMed

Volume 5 Number 39 (Issue 174)

Tuesday, November 27, 2007



## Key Inforbits

- Some serious MedWatch reports
- Chocolate – still good for you, but is it really...
- New Zealand sheds the pounds
- Personal experience – MD as drug rep.
- National influenza vaccination week
- Old adage of prevention ...

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

**Rx to OTC** ... (11/21/2007) The FDA has approved tablet, chewable tablet, and syrup formulations of **Zyrtec** (cetirizine HCl) and **Zyrtec-D** (cetirizine HCl and pseudoephedrine HCl) (on 11/9/2007), for nonprescription use. The nonprescription drug is approved for the temporary relief of symptoms due to hay fever or other respiratory allergies in adults and children 2 years of age and older. The nonprescription Zyrtec products also are approved for the relief of itching due to hives in people 6 years of age and older. The company will market two distinct Zyrtec products for each dosage form. One will provide directions for treating the symptoms of hay fever and other respiratory allergies. The other will contain directions for use to relieve the itching due to hives. Sales of the Zyrtec-D are subject to restrictions in the Combat Methamphetamine Epidemic Act, due to its pseudoephedrine content. Zyrtec is marketed and distributed by McNeil Consumer Healthcare.

<http://www.fda.gov/bbs/topics/NEWS/2007/NEW01750.html>

**New Indication** ... (11/19/2007) The FDA announced approval of **Nexavar**<sup>®</sup> (**sorafenib** by Bayer Pharmaceuticals Corp and Onyx Pharmaceuticals) for patients with **hepatocellular carcinoma**, when the cancer is inoperable. Nexavar<sup>®</sup> was originally approved in 2005 for the treatment of patients with advanced renal cell carcinoma. Hepatocellular carcinoma accounts for 80% to 90% of all liver cancers. If all of the cancer cannot be removed by surgery, the disease is usually fatal within three to six months. The American Cancer Society estimates that there will be 19,160 new cases and 16,780 deaths from cancer of the liver and intrahepatic bile duct in the United States in 2007. Sorafenib is a kinase inhibitor. It interferes with molecules that are thought to be involved in chemical messages sent within cancer cells, in the formation of blood vessels that supply tumors, and in cell death. The most common adverse reactions in these patients were fatigue, weight loss, rash or superficial skin shedding, hand or foot skin reaction, hair loss, diarrhea, anorexia, nausea and abdominal pain; ≥20% of patients had experienced at least one of these reactions. Nexavar<sup>®</sup> is supplied as 200 mg tablets; the usual dose is 400 mg twice daily on an empty stomach.

<http://www.fda.gov/bbs/topics/NEWS/2007/NEW01748.html>

**Discontinued** ... King Pharmaceuticals, Inc announced the discontinuation of the manufacture of **Procanbid** (procainamide HCl extended-release tablets) due to marketing considerations. The product, distributed by Monarch Pharmaceuticals, Inc, will remain available until current

supplies are depleted. For more information contact the Professional Information Services Dept. at 800-776-3637.

King Pharmaceuticals. Dear Prescriber Letter. November 2, 2007.

**MedWatch** ... (11/19/2007) The FDA announced the **seizure of 12,682 applicator tubes of Age Intervention Eyelash**, sold and distributed by Jan Marini Skin Research, Inc. of San Jose, CA. The product may lead to decreased vision in some users. The eyelash product is an unapproved and misbranded drug because it is promoted to increase eyelash growth. Before a new drug product may legally be marketed, it must be shown to be safe and effective, and approved by the FDA. The FDA considers the product to be an adulterated cosmetic because it contains bimatoprost, an active ingredient in an FDA-approved drug to treat elevated intraocular pressure. Use of the prescription drug in addition to the eyelash product containing the drug, may increase the risk of optic nerve damage because the extra dose of bimatoprost may decrease the prescription drug's effectiveness. Other possible adverse events may include macular edema (swelling of the retina) and uveitis (inflammation in the eye) which may lead to decreased vision. Dermatologists, estheticians, and consumers who may still have Age Intervention Eyelash should discontinue use and discard any remaining product. Read the complete 2007 MedWatch safety summary including a link to the FDA News Release regarding this issue at: <http://www.fda.gov/medwatch/safety/2007/safety07.htm#Eyelash>

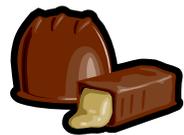
**MedWatch** ... (11/20/2007) The FDA informed healthcare professionals of reports of **suicidal thoughts and aggressive and erratic behavior in patient who have taken Chantix<sup>®</sup>**, a smoking cessation product. There are also reports of patients experiencing drowsiness that affected their ability to drive or operate machinery. The FDA is currently reviewing these cases, along with other recent reports. A preliminary assessment reveals that many of the cases reflect new-onset of depressed mood, suicidal ideation, and changes in emotion and behavior within days to weeks of initiating Chantix<sup>®</sup>. The role of Chantix<sup>®</sup> in these cases is not clear because smoking cessation, with or without treatment, is associated with nicotine withdrawal symptoms and has also been associated with the exacerbation of underlying psychiatric illness. However, not all patients had preexisting psychiatric illness and not all had discontinued smoking. Healthcare professionals should monitor patients taking Chantix<sup>®</sup> for behavior and mood changes. Patients should report behavior or mood changes to their doctor and use caution when driving or operating machinery until they know how Chantix<sup>®</sup> may affect them. Read the complete 2007 MedWatch safety summary including a link to the FDA Early Communication Sheet about an Ongoing Safety Review regarding this issue at: <http://www.fda.gov/medwatch/safety/2007/safety07.htm#Chantix>.

**MedWatch** ... (11/26/2007) Bodee LLC and the FDA announced a **nationwide recall of Encore Tablets**, a dietary supplement sold in health food stores, via the internet and by mail order nationwide and in Canada. The product was recalled because it contains potentially harmful, undeclared ingredients. One lot of the product contained aminotadalafil, an analog of tadalafil, the active ingredient of Cialis<sup>®</sup>, approved for Erectile Dysfunction. The undeclared chemical poses a threat to consumers because it may interact with nitrates found in some prescription drugs (such as nitroglycerin) and may lower blood pressure to dangerous levels. Consumers who have this product should stop using it immediately and contact their physician if they have experienced any problems that may be related to taking this product. Read the complete 2007 MedWatch safety summary including a link to the Firm's press release regarding this issue at: <http://www.fda.gov/medwatch/safety/2007/safety07.htm#Encore>

**MedWatch** ... (11/27/2007) Novartis and the FDA announced that use of **Myfortic Delayed Release Tablets during pregnancy is associated with increased risks of pregnancy loss and congenital malformations**. The pregnancy category for Myfortic has been changed to Category D (Positive evidence of fetal risk). This change is a result of postmarketing data from the United States National Transplantation Pregnancy Registry and additional postmarketing data collected in women exposed to systemic mycophenolate mofetil (MMF) during pregnancy. MMF is converted to the active ingredient in Myfortic, following oral or intravenous administration. A patient who is planning a pregnancy should not use Myfortic unless she cannot be successfully treated with other immunosuppressant drugs.

Read the complete 2007 MedWatch safety summary including a link to the Firm's Dear Healthcare Professional Letter and revised prescribing information regarding this issue at: <http://www.fda.gov/medwatch/safety/2007/safety07.htm#Myfortic>

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



**Chocolate – Good News and Bad News** ... First the **good news**: Investigators recently reported results of a study that measured coronary dilation and platelet reactivity in response to a flavonoid-rich dark chocolate (40 g, 70% cocoa) compared to a cocoa-free control in 22 heart transplant recipients. The results indicated benefit from the flavonoid-rich dark chocolate in measurements of coronary artery diameter, endothelium-dependent coronary vasomotion, and platelet adhesion. These effects should decrease atherothrombosis. The **bad news** is two-fold. First, while these results are encouraging, longer term studies assessing morbidity and mortality need to be conducted to truly assess effects. Second, it appears that the flavonol content of chocolate is important and much of these flavonols are eliminated in the various manufacturing processes; just being dark chocolate is no guarantee of flavonol content.

Flamer AJ, Hermann F, Sudano I, Spieker L, Hermann M, Cooper KA, et al. Dark chocolate improves coronary vasomotion and reduces platelet reactivity. *Circulation*. 2007 Nov 20;116:2376-2382.

Hollenberg NK, Fisher NDL. Is it the dark in the dark chocolate? *Circulation*. 2007 Nov 20;116:2360-2362.

### **Reviews of Note ...**

- Peters-Golden M, Henderson WR Jr. Leukotrienes. *N Engl J Med*. 2007 Nov 1;357(18):1841-1854.
- Guo R, Pittler MS, Ernst E. Complementary medicine for treating or preventing influenza or influenza-like illness. *Am J Med*. 2007;120:923-929.
- Majithia V, Geraci SA. Rheumatoid arthritis: Diagnosis and management. *Am J Med*. 2007;120:936-939.
- Martin SM, McCracken K, Mills MD, Robinson P, Davis V. Penetration of select antibacterials and antifungals. *Hosp Pharm*. 2007 Nov;42(11): Wall Chart.
- Kouzi SA, Nuzum DS. Arnica for bruising and swelling. *Am J Health-Syst Pharm*. 2007 Dec 1;64:2434-2443.
- Ghafoor VL, Epshteyn M, Carlson GH, Terhaar DM, Charry O, Phelps PK. Intrathecal drug therapy for long-term pain management. *Am J Health-Syst Pharm*. 2007 Dec 1;64:2447-2461.
- Agarwal R. Effects of statins on renal function. *Mayo Clin Proc*. 2007 Nov;82(11):1381-1390.

## FROM THE LAY LITERATURE about medicine ...

**New Zealand is serious about its collective health ...** A couple from England wished to emigrate to New Zealand, both for job and lifestyle. However, they both are overweight (he-BMI=42; she-BMI unreported). He went ahead of his spouse and found his application rejected due to the fact that his BMI was over the limit of New Zealand admission requirements. New Zealand's rationale is that being a small country with limited funds, it cannot afford to admit new citizens that are likely to use up critical health resources. He managed to lose enough weight; she is still trying. Where are we headed? Chapman P. New Zealand bars British man's 'fat' wife. *Telegraph.co.uk*. 2007 Nov 18.  
<http://www.telegraph.co.uk/news/main.jhtml?xml=/news/2007/11/17/wfat117.xml>



**Dr. Drug Rep ...** A lengthy but fascinating essay on one psychiatrist's foray into the world of the pharmaceutical industry as a paid speaker/consultant for a particular antidepressant medication. It is well presented and illustrates how easily and subtly influence can be exerted on individuals by virtue of money, influence, flattery and peers. So, before you steadfastly claim that you are not influenced by the myriad niceties that rain down from corporate entities, despite your education and experience, read this. Carlat D. Dr. Drug Rep. *New York Times*. 2007 Nov 25.



[http://www.nytimes.com/2007/11/25/magazine/25memoir-t.html?\\_r=1&ref=health&oref=slogin](http://www.nytimes.com/2007/11/25/magazine/25memoir-t.html?_r=1&ref=health&oref=slogin)

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

- Lindsey WT, Olin BR. Deferasirox for transfusion-related iron overload: A clinical review. *Clinical Therapeutics*. 2007 Oct;29(10):2154-2166.

## Update ...

### **National Influenza Vaccination Week --- November 26--December 2, 2007**

To help raise awareness of obtaining influenza vaccination throughout the entire influenza season, the U.S. Department of Health and Human Services, National Influenza Vaccine Summit, CDC, and other partners are conducting activities during the second annual National Influenza Vaccination Week (NIVW), November 26--December 2.  
<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5646a3.htm>



### The last "dose" ...

A stitch in time, saves nine.

--American proverb



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*Bernie R. Olin, Pharm.D., Director*