

AU InforMed

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Key Inforbits

- New vaccine, pills, indications, dosage forms
- Lots of MedWatches
- Lyme disease updates
- Disease-mongering
- Chest guidelines options
- Clarification

NEW DRUGS, and other related stuff ...

New Vaccine ... The FDA licensed a new vaccine on May 25, 2006, **Zostavax[®]** (zoster vaccine live by **Merck & Co, Inc**). It is intended to prevent shingles (herpes zoster) in people ≥ 60 years old. The vaccine is reported to prevent shingles in approximately one-half of patients receiving it and reducing the severity of disease in another portion of patients who still developed shingles.

FDA. FDA licenses new vaccine to reduce older American's risk of shingles. *FDA News*. 2006 May 26; P06-73.

<http://www.fda.gov/bbs/topics/NEWS/2006/NEW01378.html>

<http://www.zostavax.com/> (manufacturer web site)

New Pill ... An extended cycle oral contraceptive that limits a woman to four menstrual cycles per year (**Seasonique[™]**, by **Duramed Pharmaceuticals**) was approved by the FDA on May 25, 2006. Similar to Seasonale[®] however, instead of taking a placebo for the seven days following 84 days on the "pill", Seasonique's[™] seven tablets are a low-dose estrogen that is intended to minimize discomfort due to hormonal fluctuations.

FDA approves birth control pill made by Duramed. *Wall Street Journal* 2006 May 26; p. A7.

<http://www.seasonique.com/> (manufacturer web site)

New Indication ... **Thalidomide (Thalomid[®])** by Celgene Corp.) has a new indication, as approved by the FDA on May 25, 2006. It is for newly diagnosed multiple myeloma in conjunction with dexamethasone. Thalomid[®] is also indicated for erythema nodosum leprosum (leprosy). It is also labeled Pregnancy Category X as it is a known (infamous) teratogen.

<http://www.thalomid.com/> (manufacturer web site)

New Dose Form ... **IONSYS[™]** (fentanyl iontophoretic transdermal system by ALZA Corp.) was approved on May 23, 2006. This is a delivery technology for fentanyl that incorporates the drug into a device affixed to the skin and uses low level electrical current from a battery to transport drug across the skin, on patient command. It is indicated only for hospital use. It is a technology that ALZA hopes to use with other drugs.

http://www.alza.com/alza/pr_1148407686 (Manufacturer web site)

New Dose Form ... The FDA approved **Oracea™ (doxycycline capsules)** by CollaGenex Pharmaceuticals) on May 26, 2006, for the treatment of inflammatory lesions (papules and pustules) of rosacea in adult patients. Oracea™ is the first FDA-approved, orally-administered, systemically-delivered drug to treat this dermatologic condition. It consists of doxycycline 30 mg immediate release and 10 mg delayed release beads. Product release is expected in July.

<http://www.oracea.com/> (Manufacturer web site)

MedWatches ... The FDA announced reports of **acute phosphate nephropathy**, a type of acute renal failure, that is a rare, but serious adverse event associated with the use of oral sodium phosphates (OSP) for bowel cleansing. Documented cases of acute phosphate nephropathy include 21 patients who used an OSP solution (such as Fleet Phospho-soda or Fleet ACCU-PREP) and one patient who used OSP tablets (Visicol). Recommendations were offered for providers and patients when choosing and using a bowelcleanser.

Read the complete MedWatch 2006 Safety summary including, links to supporting documents and product labels, at:

<http://www.fda.gov/medwatch/safety/2006/safety06.htm#phosphate>

FDA and IVAX Pharmaceuticals, Inc. notified healthcare professionals of a **recall of Goldline brand Extra Strength Genapap 500mg (Acetaminophen) Caplets and Tablets and Extra Strength Genebs 500mg (Acetaminophen) Caplets and Tablets** due to a labeling error that may result in exceeding the maximum dosage. There have been no reports of serious illness or injury relating to this labeling matter.

Read the complete MedWatch 2006 Safety summary, including other links at:

<http://www.fda.gov/medwatch/safety/2006/safety06.htm#Goldline>

GlaxoSmithKline (GSK) and FDA notified healthcare professionals of changes to the Clinical **Worsening and Suicide Risk subsection of the WARNINGS section in the prescribing Information for Paxil® and Paxil CR®**. It is important that all patients, especially young adults and those who are improving, receive careful monitoring during paroxetine therapy regardless of the condition being treated.

Read the complete MedWatch 2006 Safety Summary, including links to the Dear Healthcare Professional Letter and the revised approved product labeling at:

<http://www.fda.gov/medwatch/safety/2006/safety06.htm#paxil>

Spectrum Laboratory Products and FDA notified healthcare professionals of the **recall of the active pharmaceutical ingredient tacrolimus**, after learning that some lots of the ingredient are subpotent. Spectrum tacrolimus API has been used by pharmacies for compounding purposes. Read the complete MedWatch 2006 Safety summary, including links to the Firm's recall press release at:

<http://www.fda.gov/medwatch/safety/2006/safety06.htm#tacrolimus>

FROM THE MEDICAL LITERATURE ...



Lyme Disease update ... The Infectious Disease Society of America has released some advice and fact sheets concerning Lyme Disease, just in time for the season. These are short, concise reviews of treatment (acute and chronic) and prevention, extending to recommendations for tick removal. A good review to have on hand. Treatment guidelines are also available on the site but date to 2000, although an updated version is due this summer.

<http://www.idsociety.org/Template.cfm?Section=Home&Template=/ContentManagement/ContentDisplay.cfm&ContentID=16279> [Review]
<http://www.idsociety.org/Template.cfm?Section=Home&CONTENTID=16277&TEMPLATE=/ContentManagement/ContentDisplay.cfm> [Fact Sheet]

Reviews of Note ...

- Abramowicz M, ed. Drugs for psychiatric disorders. *Treatment Guidelines Med Lett*. 2006 Jun;4(46):35-47.
- CDC. Prevention of hepatitis A through active or passive immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR*. 2006 May 19;55(RR07):1-23.

FROM THE LAY LITERATURE about medicine ...

Vocabulary ... Disease-mongering ... “taking something that is within normal bounds and labeling it a disease needing pharmaceutical treatment.” One physician feels that we “increasingly turning normal people into patients.” It is not a new debate but has increased with the onslaught of direct-to-consumer ads that the pharmaceutical industry consistently defends as “patient education.” Examples abound about social phobia’s requiring psychotropics, energetic kids who now have ADHD, and a new generation of insomniacs. Think about it the next time you see a commercial for a medication via your favorite media.

Stein R. Marketing the illness and the cure? Drug ads may sell people on the idea that they are sick. *Washington Post*. 2006 May 30; p. A03.

<http://www.washingtonpost.com/wp-dyn/content/article/2006/05/29/AR2006052900807.html?referrer=email>

Update ...

The following “Chest” guidelines are a popular request for us. Here are three ways to gain access to:

The Seventh ACCP Conference on Antithrombotic and Thrombolytic Therapy: Evidence-Based Guidelines (2004)

1. Hard copy in the Drug Information Center:
Hirsh J, Albers GW, Guyatt GH, Schunemann HJ, co-chairs. *The Seventh ACCP Conference on Antithrombotic and Thrombolytic Therapy: Evidence-Based Guidelines*. Chest. 2004 Sep;126(3 Suppl):163S-703S.
2. Access through the Auburn RBD Library:
Search journal titles for “Chest”
Choose “Chest [electronic/print] 1979-9999”
Choose link to “Journals @ Ovid”
Go to Volume 126 (3) September 2004 Supplement Table of Contents
Scan Table of Contents to find specific articles (24 of them)
Click on “Ovid Full Text”, then choose .pdf, if desired.
3. Internet Access:
www.chestjournal.org/contents-by-date.0.shtml
2004
September
Supplement, then Pick specific articles from Table of Contents.

NEW RESOURCES in the DILRC ...

- Helms RA, Quan DJ, Herfindal ET, Gourley DR, eds. *Textbook of Therapeutics: Disease and Drug Management*. 8th ed. Baltimore: Lippincott, Williams and Wilkins, 2006.
- Shapiro K. *Natural Products: A Case-Based Approach for Health Care Professionals*. Washington, DC: American Pharmacists Association, 2006.
- *Identi-A-Drug Reference for Drug Tablet & Capsule Identification*. 2006 ed. Stockton, CA: Therapeutic Research Center, 2005.
- Beringer P, DerMarderosian A, Felton L, Gelone S, Gennaro AR, Gupta PK, Hoover JE, et al, eds. *Remington: The Science and Practice of Pharmacy*. 21st ed. Baltimore: Lippincott, Williams and Wilkins, 2006.
- Reinders TP. *The Pharmacy Professional's Guide to Résumés, CVs, & Interviewing*. 2nd ed. Washington, DC: American Pharmacists Association, 2006.
- Perry PJ, Alexander B, Liskow BI, DeVane CL. *Psychotropic Drug Handbook*. 8th ed. Baltimore: Lippincott, Williams and Wilkins, 2007.

AUBURN HSOP FACULTY and STUDENTS in the literature ...

- Smith RE, Olin BR, Madsen JW. Spitting into the wind: The irony of treating chronic disease. *J Am Pharm Assoc*. 2006 May/June;46(3):397-400.
- Sesler A, Conrad JL, Olin BR. Serum tears and the pharmacist's role in identifying and meeting therapeutic needs. *Alabama Pharmacy*. 2006 Spring;39:16-17.
- Eiland LS, Knight P. Evaluating the off-label use of medications in children. *Am J Health-Syst Pharm*. 2006 Jun 1;63:1062-5.

Clarification ...

“BSS” was used in an article in *AU InforMed* (Feb 17, 2006) as a description for a balanced salt solution manufactured by Cytosol Laboratories that was recalled. The article was based on a report issued by the Food and Drug Administration (FDA Statement 2006 Feb 13, <http://www.fda.gov/bbs/topics/news/2006/NEW01315.html>) and the product descriptions were as described in the FDA report. Alcon Laboratories feels that this description was misused since they claim a trademark to BSS™ and BSS PLUS® for their ophthalmic sterile irrigating solutions and that the more generic term of “balanced salt irrigating solution” is more appropriate with any such product other than that manufactured by Alcon Laboratories.



The last “dose” ...

Life is a full court press.



--author unknown

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