AU InforMed

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Key Inforbits

- Vaccination recommendations for influenza
- Vaccination recommendations for varicella
- SSRI's and birth defects
- Mal de débarquement
- Flip flops have flipped – on you
- These are the times that try men's souls

NEW DRUGS, and other related stuff …

New Drug … (6/18/2007) Cephalon, Inc. has received approval from the FDA to market **Nuvigil™ (armodafinil) Tablets [C- IV]**, a non-amphetamine wake-promoting agent for the treatment of excessive sleepiness associated with obstructive sleep apnea/hypopnea syndrome (OSAHS), narcolepsy, and shift work sleep disorder (SWSD). In OSAHS, armodafinil is indicated as an adjunct to standard treatment(s) for the underlying obstruction. Armodafinil is the longer-lived r-enantiomer of modafinil, the active pharmaceutical ingredient contained in Provigil® (modafinil) Tablets [C-IV], which was approved by FDA in 1998 to improve wakefulness. The approval of Nuvigil™ is based on positive results of four double-blind, randomized, placebo-controlled studies in patients with excessive sleepiness associated with either narcolepsy, SWSD or OSAHS. Common side effects were mild to moderate in intensity and included nausea, headaches, dizziness, diarrhea, decreased appetite and upset stomach.
http://www.cephalon.com/newsroom/assets/Nuvigil_Prescribing_Information.pdf [prescribing information]

New Indication … (6/21/2007) The FDA has approved **pregabalin (Lyrica® by Pfizer) as the first drug to treat fibromyalgia**, a disorder characterized by pain, fatigue and sleep problems. Persons with fibromyalgia typically experience long-lasting or chronic pain, as well as muscle stiffness and tenderness. Fibromyalgia affects about 3 million to 6 million people in the US each year. The disorder mostly affects women and typically develops in early-to-middle adulthood. Two double-blind, controlled clinical trials, involving about 1,800 patients, support approval for use in treating fibromyalgia with doses of 300 mg or 450 mg per day. The most common side effects of pregabalin include mild-to-moderate dizziness and sleepiness. Blurred vision, weight gain, dry mouth, and swelling of the hands and feet also were reported in clinical trials. The side effects appeared to be dose-related. Pregabalin can impair motor function and cause problems with concentration and attention. Pregabalin already is approved for treating partial seizures, pain following the rash of shingles and pain associated with diabetes nerve damage (diabetic neuropathy). For a consumer article, "Living with Fibromyalgia, First Drug Approved," visit
www.fda.gov/consumer/updates/fibromyalgia062107.html
FDA approves first drug for treating fibromyalgia. *FDA News*. 2007 Jun 21; P07-107.
http://www.fda.gov/bbs/topics/NEWS/2007/NEW01656.html

New Dietary Supplement Regulations … (6/22/2007) The FDA has announced a final rule establishing regulations to require current good manufacturing practices (cGMP) for dietary supplements. The rule ensures that dietary supplements are produced in a quality manner, do not

contain contaminants or impurities, and are accurately labeled. In addition, by the end of the year, industry will be required to report all serious dietary supplement related adverse events to the FDA. The final rule includes requirements for establishing quality control procedures, designing and constructing manufacturing plants, and testing ingredients and the finished product. It also includes requirements for recordkeeping and handling consumer product complaints. If dietary supplements contain contaminants or do not contain the dietary ingredient they are represented to contain, the FDA would consider those products to be adulterated or misbranded. The aim of the final rule is to prevent inclusion of the wrong ingredients, too much or too little of a dietary ingredient, contamination by substances such as natural toxins, bacteria, pesticides, glass, lead and other heavy metals, as well as improper packaging and labeling. The final cGMP is effective August 24, 2007. To limit any disruption for dietary supplements produced by small businesses, the rule has a three-year phase-in for small businesses. More background information is available at the web site below.

FDA issues dietary supplements final rule. *FDA News*. 2007 Jun 22.
http://www.fda.gov/bbs/topics/NEWS/2007/NEW01657.html

MedWatch … (6/28/2007) The FDA notified healthcare professionals and cystic fibrosis patients that the Agency is investigating the possible connection between the use of a liquid solution of **Colistimethate that was premixed for inhalation with a nebulizer and the death of a patient with cystic fibrosis (CF)**. Colistimethate is FDA approved for intravenous or intramuscular injection for the treatment of sensitive strains of certain Gram-negative bacilli. The product is not FDA approved for use as a liquid to be inhaled via nebulizer. In this case, the drug was prepared by a pharmacy and dispensed as prescribed in premixed unit dose ready-to-use vials. Once Colistimethate is mixed into a liquid form, the product breaks down into other chemicals that can damage lung tissue. Patients should discard any unused pre-mixed liquid forms of Colistimethate. Read the complete MedWatch 2007 Safety Summary, including a link to the FDA Healthcare Professional Information Sheet and Public Health Advisory at:
http://www.fda.gov/medwatch/safety/2007/safety07.htm#Colistimethate

FROM THE MEDICAL LITERATURE …

Prevention and control of influenza … **2007-2008 Recommendations** … The groups for whom vaccination is recommended and those recommended for antiviral medications have not changed from the previous vaccination year. The primary changes to the Advisory Committee's recommendations emphasize the previous change in dosing for children 6 months to 8 years and several strategies to try to increase the vaccination coverage of the population. Unfortunately, the at-risk population is estimated to be less than 50% vaccinated. The vaccine formulation has changed this year.

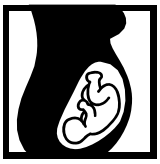
Prevention and control of influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2007. *MMWR*. 2007 Jun 29;56(Early release):1-56.
http://www.cdc.gov/mmwr/preview/mmwrhtml/rr56e629a1.htm

Prevention of varicella … **2007 Recommendations** … These replace previous Advisory Committee on Immunization Practices (ACIP) statements for prevention of varicella. The new recommendations include 1) implementation of a routine 2-dose varicella vaccination program for children, with the first dose administered at age 12 to 15 months and the second dose at age 4 to 6 years; 2) a second dose catch-up varicella vaccination for children, adolescents, and adults who previously had received 1 dose; 3) routine vaccination of all healthy persons aged >13 years without evidence of immunity; 4) prenatal assessment and

postpartum vaccination; 5) expanding the use of the varicella vaccine for HIV-infected children with age-specific CD4+T lymphocyte percentages of 15% to 24% and adolescents and adults with CD4+T lymphocyte counts >200 cells/µL; and 6) establishing middle school, high school, and college entry vaccination requirements. ACIP also approved criteria for evidence of immunity to varicella.

Prevention of varicella: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR*. 2007 Jun 22;56(RR-4):1-40.
http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5604a1.htm

SSRI's and birth defects ... two recent studies from separate established, multiple-site surveillance projects studied 9849 case infants with 5860 infant controls and 9622 case infants with 4092 infant controls. These surveillance studies showed a small chance of certain birth defects in infants born to mothers taking selective serotonin reuptake inhibitors (SSRIs). Both studies concluded that the absolute risk of birth defects while on these medications was small. An accompanying editorial does a nice job of putting these two studies in perspective with similar published studies and comes to the same conclusion. Clinicians will need to balance this information with the importance of the drug to the mother's well-being.



Louik C, Lin AE, Werler MM, Hernández-Diaz S, Mitchell AA. First-trimester use of selective serotonin-reuptake inhibitors and the risk of birth defects. *N Engl J Med*. 2007 Jun 28;356(26):2675-2683.
Alwan S, Reefhuis J, Rasmussen SA, Olney RS, Friedman JM, for the National Birth Defects Prevention Study. Use of selective serotonin-reuptake inhibitors in pregnancy and the risk of birth defects. *N Engl J Med*. 2007 Jun 28;356(26):2684-2692.
Greene MF. Teratogenicity of SSRIs – Serious concern or much ado about little? *N Engl J Med*. 2007 Jun 28;356(26):2732-2733.

Reviews of Note …

- Sicherer SH, Leung DYM. Advances in allergic skin disease, anaphylaxis, and hypersensitivity reactions to food, drugs, and insects. *J Allergy Clin Immunol*. 2007 Jun;119(6):1462-1469.
- Strawn JR, Keck PE Jr, Caroff SN. Neuroleptic malignant syndrome. *Am J Psychiatry*. 2007 Jun;164(4):870-876.
- Lauster CD, McKaveney TP, Muench S. Vildagliptin: A novel oral therapy for type 2 diabetes mellitus. *Am J Health-Syst Pharm*. 2007 Jun 15;64:1265-1273.
- Blumenthal D, Glaser JP. Information technology comes to medicine. *N Engl J Med*. 2007 Jun 14;356(24):2527-2535.
- Wareham DW, Breuer J. Herpes zoster. *BMJ*. 2007 Jun 9;334:1211-1215.
- Kockler DR, McCarthy MW. Zoster vaccine live. *Pharmacotherapy*. 2007 Jul;27(7):1013-1019.
- Dent LA, Harris KJ, Noonan CW. Tobacco interventions delivered by pharmacists: A summary and systematic review. *Pharmacotherapy*. 2007 Jul;27(7):1040-1051.

FROM THE LAY LITERATURE about medicine …

Vocabulary … **mal de débarquement** … or debarkation sickness. Many people find that when they are on a boat, plane, or a roller coaster, they sometimes have a little difficulty readjusting to terra firma. Their brain is still on the ride. This usually subsides as readjustment takes place, in minutes to hours, occasionally up to a day or two. Mal de débarquement is when readjustment doesn't happen. The

patient has motion sickness for the long term; it is often relieved by boarding a moving vehicle, eg, car, boat. It appears to be a rare event and not much is known about the problem. The usual therapies for motion sickness don't seem to work, eg, antihistamines, but through trial and error, some benzodiazepines such as diazepam or clonazepam appear effective.
Svoboda E. When seasickness persists after a return to solid ground. *New York Times*. 2007 Jun 12.
http://www.nytimes.com/2007/06/12/health/12mal.html?ref=health

Flip-flop foibles … Once again, fashion goes head-to-head with nature, and nature wins. With flip-flops being a current footwear rage, more complaints are being fielded by physicians and podiatrists. "Flip-flops were never meant to be everyday shoes" says Marybeth Crane, spokeswoman for the American College of Foot and Ankle Surgeons (www.FootPhysicians.com). Long term use can result in sore arches and heels (which can progress to serious, chronic conditions), heel calluses, hammer toes, and irritation between toes (setting up for fungal infections). What price beauty?
Trouble afoot with flip-flops. *USA Today*. 2007 Jul 2.
http://www.usatoday.com/news/health/painter/2007-07-01-flip-flops-trouble_N.htm

TIMELY TOP TECH TIP …

***AU InforMed* archives** … Looking for that special issue? Accidentally deleted last week's issue before reading? Worry no more! Archives for the past *AU InforMed* articles from 2005 to the present are available on the Harrison School of Pharmacy web site. You may go directly to the web site through this link: http://www.pharmacy.auburn.edu/dilrc/au_informed.htm
Or, you may go to the main web page for the Harrison School of Pharmacy http://www.pharmacy.auburn.edu/ (then click on "Healthcare Professionals" then "Drug Information" then AU InforMed).

The last "dose" …

"These are the times that try men's souls. The summer soldier and the sunshine patriot will, in this crisis shrink from the service of their country; but he that stands it now, deserves the love and thanks of man and woman."
- Thomas Paine [1737-1809], opening lines from The American Crisis, No. 1 [December 23, 1776]

An electronic bulletin of drug and health-related news highlights, a service of …
Auburn University, Harrison School of Pharmacy, Drug Information Center
• Phone 334-844-4400 • Fax 334-844-8366 • http://www.pharmacy.auburn.edu/dilrc/dilrc.htm
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