

AU InforMed

Volume 4 Number 2 (Issue 99)

Tuesday, January 17, 2006



Key Inforbits

- New doseform/combination/product
- Caution – real drugs in herbal products
- The flu bugs are winning
- New immunization schedule published
- Funded by an unrestricted grant ...
- Unintentional medication exposure prevention

NEW DRUGS, and other related stuff ...

New Dose Form ... The FDA has recently approved ibandronate sodium (Boniva[®]) Injection, the first intravenous medication for the treatment of postmenopausal osteoporosis. Boniva[®] Injection is administered by a health care professional once every three months.

<http://www.ptcommunity.com/Daily/DailyDetail.cfm?chosen=64458>

New Combination ... Taclonex[®], a topical ointment containing a combination of calcipotriene (0.005%) and betamethasone dipropionate (0.064%), was approved by the FDA on January 10, 2006. Taclonex[®] is indicated for the treatment of psoriasis vulgaris in adults.

<http://www.leo-pharma.com/w-site/leo/docs.nsf>

New Product/Route ... The FDA has approved, on January 9, 2006, the first immune globulin for subcutaneous (SQ) injection use to prevent serious infections in patients with primary immune deficiency diseases (PIDD). Vivaglobin[®] (by ZLB Behring) is made from human plasma collected at U.S. licensed plasma centers and provides new delivery options for PIDD patients. It is administered SQ weekly using an infusion pump, hence patients can self-administer the product at home.

<http://www.vivaglobin.com/>

MedWatch ... Novartis and FDA notified healthcare professionals of revisions to the Boxed Warning, Warnings, Contraindications, Precautions, and Adverse Reactions sections of the prescribing information for Clozaril[®] (clozapine) tablets. Recommendations from the FDA's Psychopharmacological Drugs Advisory Committee regarding the white blood cell monitoring schedule, required for all clozapine users, has resulted in modification in the monitoring schedule. Additional labeling changes address safety issues related to dementia-related psychosis, paralytic ileus, hypercholesterolemia and pharmacokinetic interaction with citalopram. Read the complete MedWatch 2006 Safety summary, including links to the Dear Healthcare professional letter and revised labeling, at:


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

MedWatch ... The FDA warned consumers not to use two unapproved drug products that are being marketed as dietary supplements for weight loss. **Emagrece Sim Dietary Supplement**, also known as the Brazilian Diet Pill, and **Herbathin Dietary Supplement** may contain several active ingredients, including controlled substances, found in prescription drugs that could lead to

serious side effects or injury. They contain chlorthalidone HCl (eg, Librium[®]), and fluoxetine HCl (eg, Prozac[®]). They were also found to contain Fenproporex, a stimulant that is not approved for marketing in the U.S. Consumers are advised not to use the Emagrece Sim and Herbathin products and to return them to the suppliers. There may be other manufacturers or suppliers of imported Emagrece Sim and Herbathin, and consumers should exercise caution in using any of these imported products.


Read complete MedWatch 2006 Safety summary, including a link to the FDA news release, at: <http://internet-dev.fda.gov/medwatch/safety/2006/safety06.htm#Brazilian>

FROM THE MEDICAL LITERATURE ...


 **Flu bugs are winning ...** A new advisory from the CDC states that the influenza virus has developed resistance against two older and common anti-influenza drugs of the adamantane class, amantadine (Symmetrel[®]) and rimantadine (Flumadine[®]). Just over the last 2-3 years, resistance has increased from around 2%-12% to over 90%. The CDC recommends not to use these drugs for treatment or prophylaxis. However, the other two marketed drugs, oseltamivir (Tamiflu[®]) and zanamivir (Relenza[®]) (neuraminidase inhibitors) are still effective and recommended. A reminder is also issued that vaccination is still the most effective means of preventing influenza.

CDC Health Alert. CDC recommends against the use of amantadine and rimantadine for the treatment or prophylaxis of influenza in the United States during the 2005-06 influenza season. January 14, 2006.

<http://www.cdc.gov/flu/han011406.htm>

 **Travel fever ...** If you have the urge to travel to exotic locales, this may temper your enthusiasm. A world-wide study of 17,353 patients was conducted from specialized travel or tropical medicine clinics treating illnesses in travelers returning from developing countries. The three most common presentations were fever, diarrhea and dermatoses. The presentation and cause was dependent on the region of the world visited. Fever was most commonly caused by malaria, diarrhea was more commonly parasite-induced rather than bacterial, and insect bites, cutaneous larva migrans and allergic rash the most common dermatologic disorders. The article has extensive breakdowns of specific diagnoses and locations.

Freedman DO, Weld LH, Kozarsky PE, Fisk T, Robins R, von Sonnenburg F, et al. Spectrum of disease and relation to place of exposure among ill returned travelers. *N Engl J Med*. 2006 Jan 12;354(2):119-30.

 **Inadvertent exposure ...** Young children are vulnerable to inadvertent exposure to prescription (Rx) and over-the-counter (OTC) medications, especially when not stored securely. In 2002, 35 children aged ≤ 4 years died from unintentional medication poisonings in the U.S. In 2003, U.S. poison control centers reported that pharmaceuticals accounted for 1,336,209 (55.8%) of unintentional chemical or substance exposures. Of those, 42.6% involved children aged < 6 years. The CDC analyzed 2001-2003 data from hospital emergency department (ED) visits and estimated that 53,517 children aged ≤ 4 years were treated annually for unintentional medication exposures; approximately 72% were in children aged 1-2 years. The most common method was leaving medication out, or in open bottles. The most common medications causing problems were central nervous system agents (e.g., acetaminophen or antidepressants) at 27%.

CDC. Nonfatal, Unintentional Medication Exposures Among Young Children --- United States, 2001-2003.

MMWR. 2006 Jan 13;55(01):1-5.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5501a1.htm>

Pandemic preparation ... The federal government has released a guide, with checklists, for

individuals and families to use in planning for an influenza pandemic. In addition to general information about the flu and pandemics, it gives information for staying generally healthy as well as what possible disruptions may occur with a pandemic and preparations that can be taken, similar to many other natural disasters.

<http://www.pandemicflu.gov/plan/pdf/guide.pdf>



Immunization schedule updated ... The CDC has updated its vaccination schedule for children and adolescents for 2006. It contains, amongst other things, recommendations for universal vaccination against hepatitis A virus and meningococcal disease and addresses the use of a recently licensed tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine. This is incorporated in their usual pictorial description of all necessary vaccinations.

CDC. Recommended Childhood and Adolescent Immunization Schedule-United States, 2006. *MMWR*. 2006 Jan 6;54(52):Q1-Q4.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5451-Immunization1.htm>

Reviews of Note ...

- Abramowicz M, ed. Drugs in the elderly. *Med Lett Drugs Ther*. 2006 Jan 16;48(1226):6-7.

FROM THE LAY LITERATURE about medicine ...

“Funded by an unrestricted grant from ...” This is a very common phrase found in journal articles, CE programs, as well as funding for professional meetings, etc. A Congressional investigation has been looking into them, concerned primarily with their questionable application as thinly veiled promotions for off-label uses, which of course, is prohibited (the pot calling the kettle black?). It’s acknowledged that off-label use of drugs is a big component of sales, estimated to be approximately one-half of all prescriptions written. Off-label prescribing is perfectly legitimate for physicians, but company promotion of off-label uses is not.

Harris G. Drug makers scrutinized over grants. *New York Times.com* 2006 Jan 11.

<http://www.nytimes.com/2006/01/11/business/11grant.html>

I’m not in the mood ... A news story from the *New York Times* based on a study from *The Journal of Sexual Medicine* that makes the point that sexual side effects from the birth control pill (aka, oral contraceptives) may be far more common than believed. This is a big deal as it is estimated that 82% of women have taken them at one time or another. Unfortunately, it is a difficult phenomenon to nail down, as a physician is quoted saying, “Sex drive has dozens of dials and switches and connections.” However, the primary message is that the oral contraceptives may cause sexual dysfunction in up to 25% of women and the effects may last for months after the medication is discontinued.

Duenwald M. When the pill arouses that urge for abstinence. *New York Times.com* 2006 Jan 10.

<http://www.nytimes.com/2006/01/10/health/10cons.html>



Health care costs continue to rise ... The overall cost of health care, including hospitals and physicians, to the cost of drugs, medical equipment, insurance and nursing home and home-health care, doubled from 1993 to 2004, said the report from the Centers for Medicare and Medicaid Services (CMS). In 2004, the U.S. spent almost \$140 billion more for health care than the year before. In 1997, health care accounted for 13.6% of the gross domestic product; in 2004 it was 16%. The health care increase of 7.9% in 2004 was almost three times the overall national

inflation rate, which was 2.7%. Perhaps the best news was that spending on drugs, increased by less than 10% for the first time in over 10 years. This is attributed to greater use of generic drugs, mail-order pharmacies, a slowdown in the introduction of costly new medications, and higher drug co-pays. Also, contrary to many implications, drug spending remains a relatively small part of the health care bill, about 10%.

Kaufman M, Stein R. Record share of economy is spent on health care. *Washington Post* 2006 Jan 10; p. A01.

<http://www.washingtonpost.com/wp-dyn/content/article/2006/01/09/AR2006010901932.html?referrer=email>

AUBURN HSOP FACULTY in the literature ...

- Townsend KA, Eiland LS. Combating influenza with antiviral therapy in the pediatric population. *Pharmacotherapy*. 2006 Jan;26(1):95-103.



The last “dose” ...

PREVENTION STRATEGIES TO REDUCE UNINTENTIONAL MEDICATION EXPOSURES AMONG YOUNG CHILDREN

- **Post the national telephone number for poison control centers (800-222-1222) on or near every home telephone.**
- **Store all medicines in secured cabinets out of reach of small children.**
- **Use child-resistant caps and always keep medication lids closed tightly after use. However, remember that even child-resistant containers are not childproof and should be stored in a secured cabinet.**
- **Whenever possible, store medicines in their original containers. Labels on original containers give important usage and safety information. Persons who transfer medications into non-child-resistant pill boxes or pill planners should be particularly vigilant about keeping them in areas not accessible to children.**
- **Discard any leftover or expired medicines by flushing them down the toilet.**
- **Avoid taking medicine in the presence of children because they tend to imitate adults.**
- **Never call medicine “candy.”**
- **Be aware of any medicines that visitors bring into the home. Make sure visitors do not leave medicines where children can easily find them (eg, in an unattended purse or suitcase).**

Sources: Adapted from recommendations of the Consumer Product Safety Commission, National Safety Council, Home Safety Council, American Academy of Pediatrics, Safe Kids Worldwide, and CDC.

CDC. Nonfatal, Unintentional Medication Exposures Among Young Children --- United States, 2001—2003. *MMWR*. 2006 Jan 13;55(01):1-5.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5501a1.htm>

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>*

Bernie R. Olin, Pharm.D., Director