AU InforMed

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Key Inforbits

- MedWatch: Provigil, Trasylol, CellCept
- Updated general vaccination guidelines
- New use for red-hot chili peppers
- Drowsy Driving Prevention Week
- Medical insurance identity theft
- Veterans Day, November 11, 2007

NEW DRUGS, and other related stuff …

New Drug … (10/30/2007) The FDA has approved **nilotinib (Tasigna™ by Novartis)** capsules for treatment of Philadelphia chromosome positive chronic myeloid leukemia (CML) in adult patients whose disease has progressed or who cannot tolerate other therapies that include imatinib (Gleevec). The FDA's approval of nilotinib includes a black box warning for possible life-threatening heart problems. Patients may lower their chances for the heart problems by taking Tasigna without food, and by avoiding grapefruit products. Patients with low blood potassium or magnesium should not use nilotinib. The most common side effects include low blood counts, rash, headache, nausea and itching. Other possible serious effects include liver damage, fluid accumulation and pancreas inflammation.
http://www.fda.gov/bbs/topics/NEWS/2007/NEW01734.html

New Salt … (10/22/2007) The FDA has approved **Renvela™ (sevelamer carbonate** by Genzyme) for the control of serum phosphorus in patients with chronic kidney disease on dialysis. Renvela™ is a next-generation version of Renagel® (sevelamer hydrochloride). Renvela™ is a calcium-free, metal-free, non-absorbed phosphate binder and will initially be available as 800mg tablets. Renvela™ offers all of the advantages of Renagel® with the added benefit of a carbonate buffer. Both drugs appear to control serum phosphorus equally to within KDOQI recommended ranges. Patients on Renvela™, however, are more likely to maintain bicarbonate levels within the recommended KDOQI ranges, and had a lower incidence of GI adverse events. Genzyme expects to launch Renvela™ for dialysis patients in the U.S. during the first quarter of next year. The company will continue to make Renagel® available, with the long-term goal of transitioning patients to Renvela™.
http://www.genzyme.com/corp/investors/GENZ%20PR-102207.asp [Genzyme press release]
http://www.genzyme.com/ [Genzyme company web site]

New Dose Form … (10/22/2007) **Voltaren® Gel** (diclofenac sodium topical gel by Novartis) 1% has received FDA approval as the first topical prescription treatment that patients can apply directly to sites of pain associated with osteoarthritis. Voltaren® Gel will be marketed in the US by the OTC business unit. It delivers effective pain relief with a favorable safety profile as its systemic absorption is 94% less than the comparable oral diclofenac treatment.
http://cws.huginonline.com/N/134323/PR/200710/1161352_5_2.html

MedWatch … (10/24/2007) The FDA and Cephalon notified healthcare professionals of Warnings added to prescribing information for **Provigil® (modafinil)**. Provigil® is indicated to improve wakefulness in adult patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea/hypopnea syndrome, and shift work sleep disorder. The **revised prescribing information include warnings** regarding serious rash, including Stevens-Johnson Syndrome (SJS) and hypersensitivity reactions, and psychiatric symptoms. Rare cases of serious or life-threatening rash, including Toxic Epidermal Necrolysis, and Drug Rash with Eosinophilia and Systemic Symptoms and Angioedema and multi-organ hypersensitivity reactions have been reported in adults and children. Provigil® is not approved for use in pediatric patients for any indication. In addition, psychiatric adverse experiences (including anxiety, mania, hallucinations, and suicidal ideation) have been reported in patients treated with Provigil®. Caution should be exercised when Provigil® is given to patients with a history of psychosis, depression, or mania. Read the complete MedWatch 2007 Safety Summary including a link to the manufacturer's Dear Healthcare Professional Letter and the revised prescribing information at:
http://www.fda.gov/medwatch/safety/2007/safety07.htm#Provigil

MedWatch … (10/25/2007) The FDA announced the Data Safety Monitoring Board's recommendation to stop patient enrollment in the **aprotinin (Trasylol)** treatment group arm of the Blood conservation using antifibrinolytics: A randomized trial in a cardiac surgery population (BART) study. The BART study was designed to test the hypothesis that aprotinin was superior to epsilon-aminocaproic acid and tranexamic acid in decreasing the occurrence of massive bleeding in association with cardiac surgery. The preliminary findings suggest that, comparatively aprotinin increases the risk of death. Read the complete MedWatch 2007 Safety Summary including a link to Early Communication information regarding this issue at:
http://www.fda.gov/medwatch/safety/2007/safety07.htm#Aprotinin

MedWatch … (10/29/2007) The use of CellCept (mycophenolate mofetil) is associated with increased risk of first trimester pregnancy loss and congenital malformations, especially external ear and facial abnormalities including cleft lip and palate, and anomalies of the distal limbs, heart, esophagus, and kidney. The **pregnancy category for CellCept has been changed from Category C (risk of fetal harm cannot be ruled out) to Category D (positive evidence of fetal risk)**. Within one week of beginning CellCept therapy, women of childbearing potential should have a negative serum or urine pregnancy test. In addition, women of childbearing potential (including pubertal girls and peri-menopausal woman) must receive contraceptive counseling and use effective contraception. CellCept reduces blood levels of the hormones in the oral contraceptive pill and could theoretically reduce its effectiveness. See the Dear Healthcare Professional Letter for additional recommendations for women of childbearing potential.
Read the complete MedWatch 2007 Safety Summary including a link to the Dear Healthcare Professional Letter and revised prescribing information, at:
http://www.fda.gov/medwatch/safety/2007/safety07.htm#CellCept2

FROM THE MEDICAL LITERATURE …

Recommended Adult Immunization Schedule, US, Oct 2007--Sep 2008 … The Advisory Committee on Immunization Practices (ACIP) has approved the Adult Immunization Schedule for October 2007-September 2008. Some of the changes for this year's immunization schedule include:

- The varicella vaccine is recommended for all adults without evidence of immunity to varicella.
- Zoster vaccine has been added, recommended for persons aged >60 years.
- The indication "recipients of clotting factor concentrates" has been removed from the column heading "chronic liver disease" because only one vaccine has this recommendation.
- Health-care personnel can receive either trivalent inactivated influenza vaccine (TIV) or live, attenuated influenza vaccine (LAIV).
- Indications for influenza vaccine have been extended to include persons in the "asplenia" risk group.
- Zoster vaccine is recommended for all indications except pregnancy, immunocompromising conditions, and HIV, where it is contraindicated.

Advisory Committee on Immunization Practices (ACIP). Recommended Adult Immunization Schedule-United States, October 2007-September 2008. *MMWR*. 2007 Oct 19;56(41):Q1-Q4.
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5641-Immunizationa1.htm

Reviews of Note …

- Qaseem A, Snow V, Shekelle P, Sherif K, Wilt TJ, Weinberger S, Owens DK for the Clinical Efficacy Assessment Subcommittee of the American College of Physicians. Diagnosis and Management of stable chronic obstructive pulmonary disease: A clinical practice guideline from the American College of Physicians. *Ann Intern Med*. 2007 Nov 6;147:633-638.
- Wilt TJ, Niewoehner D, MacDonald R, Kane RL. Clinical Guidelines: Management of stable chronic obstructive pulmonary disease: a systematic review for a clinical practice guideline. *Ann Intern Med*. 2007 Nov 6;147:639-653.
- National surveillance for asthma – United States, 1980-2004. *MMWR*. 2007 Oct 19;56(SS-8):1-54. http://www.cdc.gov/mmwr/preview/mmwrhtml/ss5608a1.htm

FROM THE LAY LITERATURE about medicine …

Dispensing physicians … **they're baaack** … but they have never really left. It's estimated that less than 10% of physicians in the U.S. sell prescriptions to their patients; but a marketing firm estimates that it could grow to 25% in 5 to 10 years. Emphasis was put on the convenience to some patients and that there are companies that service physician offices with prepackaged bottles that just need a label. Some states prohibit such activity, but others do not. The skipping of a critical double check system involving the pharmacist was alluded to, but it was subtle. At least the point was made that the prescriptions were rarely cheaper in the physician office.

Kritz FL. Doctor? Or Druggist? *Washington Post*. 2007 Oct 30; p. HE01.
http://www.washingtonpost.com/wp-dyn/content/article/2007/10/26/AR2007102602484.html?wpisrc=newsletter

Hot topic … **Red hot chili peppers** may do more than spice up the food. Capsaicin, the active ingredient, has been used for years as a topic treatment for sore muscles and joints. Now it is being investigated as a post-surgical analgesic. From the American Society of Anesthesiologists, a study showed increased pain relief after hernia repair, when a purified preparation of capsaicin was applied to the wound. It has also shown decreased postoperative pain and decreased need for morphine after knee surgery. It is a one time application while the patient is still under anesthesia, since the application would be

extremely painful otherwise. There may be many other applications, including a mixture with lidocaine and potential treatment of cancer pain, for dental procedures, etc.
Neergaard L (Associated Press). Doctors test hot sauce for pain relief. *USA Today*. 2007 Oct 29.
http://www.usatoday.com/news/health/2007-10-29-hot-sauce-pain_N.htm

Update …

Drowsy Driving Prevention Week, November 5-11, 2007 … Many people are unaware of the often fatal consequences of driving while drowsy. In the 2005 Sleep in America poll, 37% of respondents (representing 103 million U.S. residents) reported that they had fallen asleep while driving during the preceding year. Even experienced long-distance truck drivers are vulnerable; 47.1% of those surveyed had fallen asleep while driving a truck at some time. Groups found to be at increased risk for drowsy driving include men aged <26 years, night-shift workers, commercial drivers, and persons with undiagnosed or untreated sleep disorders.

Information about healthy sleep practices is available from the National Sleep Foundation at http://www.sleepfoundation.org/site, from CDC at http://www.cdc.gov/sleep, and from the National Heart, Lung, and Blood Institute at http://www.nhlbi.nih.gov/health/public/sleep.
Educational materials regarding drowsy driving are available at http://www.nhtsa.dot.gov/people/outreach/safesobr/21qp/html/coming_attractions/wake_up.html.
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5643a5.htm

TIMELY TOP TECH TIP …

If your wallet/purse is stolen … Driver's license and credit cards aren't your only worry. Now also targeted is your health care ID card, pharmacy card and insurance cards, that the unscrupulous will use for **medical identity theft**. Stolen cards have been used to gain many thousands of dollars in medical benefits. In addition to the costs, the victim may have false information in the medical record (eg, allergies/not), diagnoses and treatments may become part or your record and haunt you if applying for a job (what about that cancer problem?) or applying for life insurance; and, charges may go against a policy lifetime limit. A rule of thumb, be very suspicious of "free" medical services.

Knight VE. Escalating health-care costs fuel medical identity theft: Patients are told to guard ID cards like other plastic. *Wall Street Journal*. 2007 Oct 11; p. D3.

The last "dose" …

History does not long entrust the care of freedom to the weak or the timid.
— General Dwight D. Eisenhower [1890-1969]

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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