



## Key Inforbits

- Fatal skin reactions with carbamazepine
- Preferred meningococcal vaccine
- Teenage drug use declining – on some fronts
- Free syringes and free antidote
- Professional nitpicker
- Christmas thoughts from the Grinch

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

**New Drug** ... (12/13/2007) The FDA has approved **sapropterin dihydrochloride (Kuvan<sup>TM</sup>)** by BioMarin) tablets. Kuvan<sup>TM</sup> is indicated to reduce blood phenylalanine (Phe) levels in patients with hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4) responsive phenylketonuria (PKU); it is to be used in conjunction with a Phe-restricted diet. The recommended starting dose of Kuvan<sup>TM</sup> is 10 mg/kg/day taken once daily for up to a month. If there is no response, the dose may be increased to 20 mg/kg/day for up to a month. The dose may be adjusted within a range of 5 to 20 mg/kg/day in patients who respond to Kuvan<sup>TM</sup>. The drug is available immediately.

<http://www.biomarinpharm.com/> (BioMarin web site)

<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.DrugDetails>  
(FDA approval history and label)

**Discontinued** ... (10/1/2007) Roche has advised health professionals that it is discontinuing the production of **Roferon<sup>®</sup>-A (interferon alfa-2a, recombinant)**. Supplies will be allowed to deplete and should be exhausted by early to mid-2008. It is a marketing decision unrelated to safety or efficacy of the product.

<http://www.fda.gov/cder/drug/shortages/Roferon.pdf>

**MedWatch** ... (12/4/2007) The FDA requested that manufacturers update the prescribing information for desmopressin to include new safety information about severe hyponatremia and seizures. Certain patients, including children treated with the intranasal formulation of the drug for primary nocturnal enuresis (PNE), are at risk for developing severe hyponatremia that can result in seizures and death. As such, desmopressin intranasal formulations are no longer indicated for the treatment of primary nocturnal enuresis and should not be used in hyponatremic patients or patients with a history of hyponatremia. All desmopressin formulations should be used cautiously in patients at risk for water intoxication with hyponatremia.

Read the complete MedWatch 2007 Safety Summary including a link to the FDA Information for Healthcare Professional Sheet regarding this issue at:

<http://www.fda.gov/medwatch/safety/2007/safety07.htm#Desmopressin>

**MedWatch** ... (12/11/2007) The FDA informed healthcare professionals of the issuance of the Agency's follow-up communication regarding its review of **safety data for the drugs omeprazole and esomeprazole** that raised concerns about a potential increased risk of heart

problems for patients treated with these drugs. The FDA continues to believe that long-term use of omeprazole or esomeprazole is not likely to be associated with an increased risk of heart problems and recommends that healthcare providers continue to prescribe and patients continue to use these products in the manner described in the labeling for the two products.

Read the complete MedWatch 2007 Safety Summary including a link to the follow-up FDA communication regarding this issue at:

<http://www.fda.gov/medwatch/safety/2007/safety07.htm#Omeprazole>

**MedWatch** ... (12/12/2007) The FDA informed healthcare professionals that **dangerous or even fatal skin reactions** (Stevens Johnson syndrome and toxic epidermal necrolysis), that can be caused by **carbamazepine** therapy, are significantly more common in patients with a particular human leukocyte antigen (HLA) allele, HLA-B\*1502. This allele occurs almost exclusively in patients with ancestry across broad areas of Asia, including South Asian Indians. Patients with ancestry from these areas should be screened before starting treatment with carbamazepine. If positive, carbamazepine should not be started unless the expected benefit clearly outweighs the increased risk. Patients who have been taking carbamazepine for more than a few months without developing skin reactions are at low risk of these events ever developing from carbamazepine. Read the complete MedWatch 2007 Safety Summary including a link to the FDA Information for Healthcare Professionals Sheet and the Drug Information Page regarding this issue. <http://www.fda.gov/medwatch/safety/2007/safety07.htm#carbamazepine>

**MedWatch** ... (12/14/2007) Merck & Co. and the FDA announced a **voluntary recall of eleven lots of PedvaxHIB and two lots of COMVAX vaccines**. The vaccines were recalled because the manufacturer cannot assure sterility of the affected lots. Sterility tests of the vaccine lots themselves have not found any contamination. The affected doses were distributed in the U.S. starting in April 2007. See the FDA Consumer Update for a list of the specific lots of each vaccine recalled. Read the complete MedWatch 2007 Safety Summary including a link to the FDA Consumer Update regarding this issue at:

<http://www.fda.gov/medwatch/safety/2007/safety07.htm#PedvaxHIB>

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

**Preferred vaccine for meningococcal disease ...** The Advisory Committee on Immunization Practices (ACIP) revised its recommendation to state that Quadrivalent Meningococcal Conjugate vaccine (MCV4; Menactra<sup>®</sup>, Sanofi Pasteur) is preferable to meningococcal polysaccharide vaccine (MPSV4; Menomune<sup>®</sup>, Sanofi Pasteur) for vaccination of children aged 2 to 10 years who are at increased risk for meningococcal disease. These children include travelers to or residents of countries in which meningococcal disease is hyperendemic or epidemic, children who have terminal complement component deficiencies, and children who have anatomic or functional asplenia. Additionally, MCV4 is preferred to MPSV4 for use among children aged 2 to 10 years for control of meningococcal disease outbreaks. Providers may elect to vaccinate children aged 2 to 10 years who are infected with human immunodeficiency virus (HIV). For children aged 2 to 10 years who have previously received MPSV4 and remain at increased risk for meningococcal disease, ACIP recommends vaccination with MCV4 at 3 years after receipt of MPSV4. Children who last received MPSV4 more than 3 years ago and remain at risk for meningococcal disease should be vaccinated with MCV4 as soon as possible. For children at lifelong increased risk for meningococcal disease, subsequent doses of MCV4 likely will be needed.



Notice to readers. Recommendation from the Advisory Committee on Immunization Practices (ACIP) for use of quadrivalent meningococcal conjugate vaccine (MCV4) in children aged 2-10 years at increased risk for invasive meningococcal disease. *MMWR*. 2007 Dec 7;56(48):1265-6.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5648a4.htm>

**Teen drug use down** ... according to the 33<sup>rd</sup> national survey in Monitoring the Future (MTF) series conducted by the University of Michigan's Institute for Social Research.

Some of the more prominent numbers include: 8<sup>th</sup>, 10<sup>th</sup>, and 12<sup>th</sup> grader use of illicit drugs continues to decline with rates now at 13%, 28% and 36%, respectively.



Marijuana is still the most widely used of all illicit drugs, though decreasing. Prescription drug use (outside legitimate medical uses) is increasing, with OxyContin<sup>®</sup> (oxycodone) and Vicodin<sup>®</sup> (acetaminophen/hydrocodone) mentioned specifically. Also noted was continued use at about the same rate as 2006 of over-the-counter products containing dextromethorphan; alcohol use has also continued to decline.



Johnston, L. D., O'Malley, P. M., Bachman, J. G. & Schulenberg, J. E. (December 11, 2007). "Overall, illicit drug use by American teens continues gradual decline in 2007." University of Michigan News Service: Ann Arbor, MI. [Online]. Available: [www.monitoringthefuture.org](http://www.monitoringthefuture.org) ; accessed 12/15/2007.

### Reviews of Note ...

- Masoumi A, Reed-Gitomer B, Kelleher C, Schrier RW. Potential pharmacological interventions in polycystic kidney disease. *Drugs*. 2007;67(17):2495-2510.
- Panés J, Gomollón F, Taxonera C, Hinojosa J, Clofent J, Nos P. Crohn's disease: A review of current treatment with a focus on biologics. *Drugs*. 2007;67(17):2511-2537.
- Hoy SM, Scott LJ. Etanercept: A review of its use in the management of ankylosing spondylitis and psoriatic arthritis. *Drugs*. 2007;67(17):2609-2633.
- Unützer J. Late-life depression. *N Engl J Med*. 2007 Nov 29;357(22):2269-2276.
- Battino D, Tomson T. Management of epilepsy during pregnancy. *Drugs*. 2007;67(18):2727-2746.
- Deeks ED, Keam SJ. Rosiglitazone: A review of its use in type 2 diabetes mellitus. *Drugs*. 2007;67(18):2747-2779.
- Canto JG, Goldberg RJ, Hand MM, Bonow RO, Sopko G, Pepine CK, Long T. Symptom presentation of women with acute coronary syndromes: Myth vs reality. *Arch Intern Med*. 2007 Dec 10/24;167(22):2405-2413.

### FROM THE LAY LITERATURE about medicine ...

**Some antidote with those syringes?** ... A relatively new program in some big cities (eg, New York, San Francisco, Chicago) is training narcotic abusers (primarily heroin) in the use of the antidote naloxone for the event when the users overindulge and go into respiratory depression. The program is not without controversy. Anecdotal evidence indicates it may save lives and others speculate that it may simply encourage even more use with a "safety net" available. Everyone agrees that there is little hard evidence to evaluate, but that may change in the next few years. The sellers are likely happy, too; fewer deaths, more product sold.



Hurley D. Emergency antidote, direct to addicts. *New York Times*. 2007 Dec 11.

[http://www.nytimes.com/2007/12/11/science/11hero.html?\\_r=1&ref=health&oref=slogin](http://www.nytimes.com/2007/12/11/science/11hero.html?_r=1&ref=health&oref=slogin)

**Job Title - Professional Nitpicker ...** In the most literal sense, picking nits (lice eggs) from hair. This appears to be an up and coming profession, particularly in areas of chronic infestation. At \$50/hour a professional Nitpicker will come in, delouse those infected (usually school-age children), provide treatment regimens and give detailed instructions on cleaning to rid the house of lice. There is at least one business enterprise set up for this purpose, "Hair Fairies" based in Los Angeles, but also with salons (yes, salons) in San Francisco, New York and Chicago. Anyone with children knows of this scourge; there is some controversy as to their usefulness, but there seems to be a niche.



niche.

Agnvall E. Lice work, if you can get it. *Washington Post*. 2007 Dec 18; p. HE01.

[http://www.washingtonpost.com/wp-](http://www.washingtonpost.com/wp-dyn/content/article/2007/12/14/AR2007121401815.html?wpisrc=newsletter)

[dyn/content/article/2007/12/14/AR2007121401815.html?wpisrc=newsletter](http://www.washingtonpost.com/wp-dyn/content/article/2007/12/14/AR2007121401815.html?wpisrc=newsletter)

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

Eiland EH III, Robinson JB. Effect of linezolid on the occurrence of vancomycin-resistant enterococci. *Am J Health-Syst Pharm* 2007;64:2535-2536 letter to editor

### **TIMELY TOP TECH TIP ...**

**Phishing Scams ...** Fraudulent e-mail messages are occasionally received, appearing to come from legitimate sources (e.g., your bank, eBay, PayPal). These e-mails are phishing scams that direct you to a spoofed Web site and ask you for private information (eg, your password, your credit card number or other personal information). The perpetrators of these scams then use this private information to commit identity theft. **Best advice:** never click the links provided in e-mail messages and never respond to any e-mail that asks for personal information. No legitimate business will ask you to provide this information in the form of an e-mail or Web site. If you feel the message may be legitimate, go directly to the company's Web site by typing it in your browser or contact the company to see if you really do need to take the action described in the e-mail message.



### **The last "dose" ...**

And the Grinch, with his Grinch-feet ice cold in the snow, stood puzzling and puzzling, how could it be so? It came without ribbons. It came without tags. It came without packages, boxes or bags. And he puzzled and puzzled 'till his puzzler was sore. Then the Grinch thought of something he hadn't before. What if Christmas, he thought, doesn't come from a store. What if Christmas, perhaps, means a little bit more.

From "How the Grinch Stole Christmas" by Theodore Seuss Geisel (Dr. Seuss) [1904 - 1991]

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