AU InforMed

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Key Inforbits

- Many MedWatches
- Glucosamine for osteoarthritis – NOT
- New therapeutic guidelines for dementia
- Melatonin as a sleep aid for kids
- Sleep Awareness Week
- Optimism …

NEW DRUGS, and other related stuff …

New Drug … (2/27/2008) The FDA has approved **Arcalyst (rilonacept, an Interleukin-1 blocker**, by Regeneron Pharmaceuticals Inc.) as an orphan drug, for the long term treatment of two Cryopyrin-Associated Periodic Syndromes (CAPS) disorders: Familial Cold Auto-Inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS). Symptoms of both of these disorders include inflammation such as joint pain, rash or skin lesions, fever and chills, eye redness or pain; however MWS is associated with more severe inflammation and may include hearing loss or deafness. In addition, some MWS patients may also be affected by the buildup of a protein substance that damages organs and tissue (amyloidosis). The FCAS and MWS disorders affect about 300 people in the US. The most commonly reported side effects associated with use of Arcalyst were injection-site reactions and upper respiratory infections.
For more information on the Orphan Drug Act, visit: www.fda.gov/orphan/.
http://www.fda.gov/bbs/topics/NEWS/2008/NEW01801.html

New Drug … (2/29/2008) The FDA has approved **desvenlafaxine (PRISTIQ™ by Wyeth** Pharmaceuticals), a once-daily serotonin-norepinephrine reuptake inhibitor (SNRI), to treat adult patients with major depressive disorder (MDD). It was approved at a once-daily 50-mg dose that does not require titration. FDA approval was subject to several post-marketing commitments, including conducting and submitting data from a new long-term maintenance (relapse prevention) study, a sexual dysfunction study, pediatric studies and a study exploring lower doses. The agency also requested an additional non-clinical toxicity study. Wyeth expects to begin shipping PRISTIQ to wholesalers beginning in the second quarter of 2008. Good timing since Effexor XR® (venlafaxine) will soon be losing patent protection.
http://www.wyeth.com/hcp/pristiq/home [Wyeth web site]
Saul S. FDA approves Wyeth antidepressant. *New York Times*. 2008 Mar 1.
http://www.nytimes.com/2008/03/01/business/01wyeth.html?_r=1&ex=1362200400&en=fe7b8de4e78ea9f7&ei=5088&partner=rssnyt&emc=rss&oref=slogin

MedWatch … (2/15/2008) PriCara and Sandoz Inc. announced a **nationwide recall** of all lots of 25 mcg/hr **Duragesic Patches** sold in the US. The product is being recalled because the patches may have a cut along one side of the drug reservoir which may result in the release of fentanyl gel that may expose patients or caregivers directly to fentanyl gel on the skin. Fentanyl is a potent Schedule II opioid and exposure to the gel may lead to serious adverse events, including respiratory depression and possible fatal overdose. Patches with a cut edge should not be used.

These recalled patches have expiration dates on or before December 2009 and are all manufactured by ALZA Corporation. Read the complete 2008 MedWatch Safety Summary, including a link to the FDA Firm Press Release regarding this issue at:
http://www.fda.gov/medwatch/safety/2008/safety08.htm#Duragesic

MedWatch … (2/20/2008) Actavis Inc. announced a **nationwide recall** of lots of **Fentanyl transdermal system CII Patches** sold in the US and labeled with an Abrika or Actavis label. The product may have a fold-over defect which can cause the patch to leak and expose patients or caregivers directly to the fentanyl gel. Exposure to fentanyl gel may lead to serious adverse events, including respiratory depression and possible fatal overdose. The lots covered by this recall include doses of 25, 50, 75, and 100 mcg/hr and are listed in the firm's press release.
See the complete MedWatch 2008 safety summary, including a link to the firm's press release:
http://www.fda.gov/medwatch/safety/2008/safety08.htm#Fentanyl

MedWatch … (2/27/2008) Biogen Idec, Elan and FDA notified healthcare professionals of reports of **clinically significant liver injury**, including markedly elevated serum hepatic enzymes and elevated total bilirubin, occurred as early as six days **after the first dose of Tysabri** (natalizumab). The combination of transaminase elevations and elevated bilirubin without evidence of obstruction is recognized as an important predictor of severe liver injury that may lead to death or the need for a liver transplant in some patients. Tysabri should be discontinued in patients with jaundice or other evidence of significant liver injury. Read the complete 2008 MedWatch Safety Summary, including a link to the manufacturer's Dear Healthcare Professional Letter and prescribing information for Tysabri at:
http://www.fda.gov/medwatch/safety/2008/safety08.htm#Tysabri

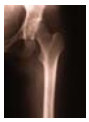
MedWatch … (2/29/2008) FDA announced the **correct way to use Spiriva and Foradil inhalation powder capsules**. FDA and the National Poison Control Center have received many reports of patients swallowing Spiriva and Foradil capsules rather than placing the capsules in the inhalation devices. Both products are to be used in the HandiHaler (Spiriva) and Aerolizer (Foradil) devices to deliver the medicine to the lungs to improve breathing in patients with asthma, chronic obstructive lung disease and bronchitis. Both products will not treat a patient's breathing condition if the contents of a capsule are swallowed rather than inhaled. Healthcare professionals should discuss with patients how the correct use the Spiriva HandiHaler or Foradil Aerolizer. See the Public Health Advisory on the correct use of both products.
Read the complete 2008 MedWatch Safety Summary, including a link to the FDA's Public Health Advisory regarding this issue at:
http://www.fda.gov/medwatch/safety/2008/safety08.htm#Spiriva

UPDATE … **Baxter Healthcare** and the FDA informed healthcare professionals of a voluntary **recall of all Heparin multi-dose and single-use vials, and Heparin lock flush solutions**. This is apparently related to the fact that the number of deaths potentially attributed to use of heparin manufactured in a Chinese laboratory has risen from 4 to 21; this is in addition to several hundred adverse reaction reports. Further investigation keeps turning up more lapses in the quality assurance system. Full disclosure and resolution promises to be ugly.
Read the MedWatch 2008 safety summary, including links to the Public Health Update, press release, and the previous safety alert information, at:
http://www.fda.gov/medwatch/safety/2008/safety08.htm#HeparinInj2
Bogdanich W. Blood thinner might be tied to more deaths. *New York Times*. 2008 Feb 29.
http://www.nytimes.com/2008/02/29/us/29heparin.html?ref=health

MedWatch … (3/3/2008) Roche and FDA informed healthcare professionals of **neuropsychiatric events associated with the use of Tamiflu**, in patients with influenza. These symptoms, as described in post marketing reports mostly from Japan, include delirium and abnormal behavior leading to injury, and in some cases resulting in fatal outcomes. These events were reported primarily among pediatric patients and often had an abrupt onset and rapid resolution. Patients with influenza should be closely monitored for signs of abnormal behavior. If neuropsychiatric symptoms occur, evaluate the risks and benefits of continuing treatment.
See the MedWatch 2008 safety summary, including links to the Dear Healthcare Professional letter and Tamiflu Prescribing Information, at:
http://www.fda.gov/medwatch/safety/2008/safety08.htm#Tamiflu

FROM THE MEDICAL LITERATURE …

Glucosamine for osteoarthritis … Yet another randomized, placebo-controlled trial of 222 hip osteoarthritis patients demonstrated that glucosamine, 1500 mg daily was no more effective than placebo. The trial was conducted in the Netherlands and patients were recruited through primary care providers. Demographic and clinical variables were similar and measurements were the Western Ontario and McMaster Universities (WOMAC) pain and function subscales, in addition to joint space narrowing, over 24 months. Even in a more "friendly" environment such as Europe, alternative therapy benefit is difficult to prove in scientific trials.



Rozendaal RM, Koes BW, van Osch GJVM, Uitterlinden EJ, Garling EH, Willemsen SP, et al. Effect of glucosamine sulfate on hip osteoarthritis: A randomized trial. Ann Intern Med. 2008;148:268-277.

Dementia treatment guidelines and evidence … The latest treatment guidelines for dementia have been published by the American College of Physicians.[1] These guidelines were based on a systematic review of the available cholinesterase inhibitors and memantine used for treating dementia.[2] This review looked at 96 publications representing 59 studies that fit predefined criteria for population, trial design and quality scores. Assessments were based on cognition, global assessment, behavior and quality of life. The conclusion of the review was that these agents "can result in statistically significant but clinically marginal improvement in measures of cognition and global assessment of dementia." The guidelines have three major, but very general, recommendations based on the assessment of evidence as low-to-moderate quality.

[1]Qaseem A, Snow V, Cross Jr JT, Forciea MA, Hopkins Jr R, Shekelle P, et al for the Joint Americna College of Physicians/American Academy of Family Physicians Panel on Dementia. Current pharmacologic treatment of dementia: A clinical practice guideline from the American College of Physicians and the American Academy of Family Physicians. Ann Intern Med. 2008 Mar 4;148:370-378.

[2]Raina P, Santaguida P, Ismaila A, Patterson C, Cowan D, Levine M, Booker L, Oremus M. Effectiveness of cholinesterase inhibitors and memantine for treating dementia: Evidence review for a clinical practice guideline. Ann Intern Med. Mar 4;148:379-397.

Reviews of Note …

- Choy CK, Rodgers JE, Nappi JM, Haines ST. Type 2 diabetes mellitus and heart failure. Pharmacotherapy. 2008 Feb;28(2):170-192.
- See S, Ginzburg R. Skeletal muscle relaxants. Pharmacotherapy. 2008 Feb;28(2):207-213.
- Corbett SM, Montoya ID, Moore FA. Propofol-related infusion syndrome in intensive care patients. Pharmacotherapy. 2008 Feb;28(2):250-258.

- Harris IM, Baker E, Berry TM, Halloran MA, Lindauer K, Ragucci KR, McGivney MS, Taylor T, Haines ST, for the American College of Clinical Pharmacy. Developing a business-practice model for pharmacy services in ambulatory settings. Pharmacotherapy. 2008 Feb;28(2):285. Full text at www.pharmacotherapy.com
- Varon J. Treatment of acute severe hypertension: Current and newer agents. Drugs. 2008;68(3):283-297.
- Croom KF, Curran MP. Sildenafil: A review of its use in pulmonary arterial hypertension. Drugs. 2008;68(3):283-397.

FROM THE LAY LITERATURE about medicine …

Melatonin – wonder drug for kids? … A recent article has touted the benefits of using melatonin as a sleep aid in children, mostly teenagers. Using several case descriptions, one word stands out, "miraculous." The article goes on to describe some of the limitations of melatonin and more importantly, the limitation of our knowledge of it used in sleep. It also discusses some of the problems with supplements in general and the reluctance of physicians to endorse its use. However, the tone was set in the first paragraphs.

Galewitz P. Kids tucked in with a dose of melatonin. *USA Today*. 2008 Mar 2.
http://www.usatoday.com/news/health/2008-03-02-kids-melatonin_N.htm

Update …

National Sleep Awareness Week, March 3-9, 2008 … The National Sleep Foundation recommends that healthy adults sleep 7 to 9 hours daily. Younger persons need even more sleep. Sufficient sleep is increasingly being recognized as an essential aspect of health maintenance. Sleep-related complaints are common; 60 million persons in the United States experience them, and 20% of patients consulting a general practitioner report sleep disturbances. Various health and emotional issues may affect sleep and lack of sleep decreases daily performance. Additional information about public health implications of sleep is available at http://www.cdc.gov/sleep. Additional information regarding sufficient sleep is available from the National Sleep Foundation at http://www.sleepfoundation.org/site.

Notice to readers: National sleep awareness week, March 3-9, 2008. MMWR. 2008 Feb 29;57(8):206-207.
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5708a4.htm

The last "dose" …

"Perpetual optimism is a force multiplier"
--Colin Powell [1937 -]

An electronic bulletin of drug and health-related news highlights, a service of …
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