

AU InforMed

Volume 6 Number 5 (Issue 182)

Monday, February 4, 2008



Key Inforbits

- Chantix[®] and neuropsychiatric effects
- Lifestyle makes a difference, about 14 years
- Cost of diabetes calculated
- Ototoxic ear wax removal
- Morgellons Disease, new or a comeback?
- Grateful heart ...

NEW DRUGS, and other related stuff ...

New Drug ... (1/29/2008) The FDA has approved **EMEND[®] (fosaprepitant dimeglumine** by Merck) for Injection, a new intravenous therapy for the prevention of chemotherapy-induced nausea and vomiting. EMEND[®] (fosaprepitant dimeglumine) for injection is an intravenous prodrug of the oral formulation of EMEND[®] (aprepitant). Fosaprepitant is rapidly converted in the body to aprepitant. EMEND[®] for Injection is approved for use in combination with other antiemetic medicines for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic and highly emetogenic cancer chemotherapy, including high-dose cisplatin. EMEND[®] for Injection and oral EMEND[®], when used in combination with other antiemetics, are only used to help prevent nausea and vomiting caused by chemotherapy. They are not used to treat nausea and vomiting after they start.

http://www.merck.com/newsroom/press_releases/product/2008_0129.html [Press Release]

New Indication ... (1/18/2008) **Colsevelam HCl (Welchol[™]** by Daiichi Sankyo) is a bile acid sequestrant previously indicated to lower low density lipoprotein cholesterol (LDL).

It has now been approved by the FDA to improve glycemic control (measured as hemoglobin A1C in adults with type 2 diabetes mellitus), in combination with other antidiabetic medications.

http://www.sankyopharma.com/news/pdfs/Welchol_final_press_release.pdf

MedWatch ... (1/31/2008) **NuCel Labs** and FDA informed consumers and healthcare professionals of a voluntary nationwide **recall of all Eye Drops and Eye/Ear Wash Products**. The products were recalled after testing indicated the presence of bacteria and particulate matter, deeming these products **non-sterile**. Non-sterile eye drops pose an unacceptable risk of causing eye infections, which in rare cases could lead to blindness. No illnesses or injuries have been reported to date. There are no lot numbers or expiration dates on the products. Consumers who have the product should discontinue use of the product and return it to NuCel Lab. See the manufacturer's press release for return shipping information.

Read the complete 2008 MedWatch Safety Summary, including a link to the Manufacturer's Press Release regarding this issue at:

<http://www.fda.gov/medwatch/safety/2008/safety08.htm#NuCel>

MedWatch ... (1/31/2008) **Suicidality and antiepileptic drugs** ... FDA announced that the Agency has analyzed reports of suicidality (suicidal behavior or ideation) from placebo-controlled clinical studies of eleven drugs used to treat epilepsy as well as psychiatric disorders

and other conditions. In the FDA's analysis, patients receiving antiepileptic drugs had approximately twice the risk of suicidal behavior or ideation (0.43%) compared to patients receiving placebo (0.22%). The increased risk of suicidal behavior and suicidal ideation was observed as early as one week after starting the antiepileptic drug and continued through 24 weeks. The results were generally consistent among the eleven drugs. The relative risk for suicidality was higher in patients with epilepsy compared to patients who were given one of the drugs in the class for psychiatric or other conditions. The drugs included in the analyses include (some of these drugs are also available in generic form):

Carbamazepine (marketed as Carbatrol, Equetro, Tegretol, Tegretol XR)	Oxcarbazepine (marketed as Trileptal)
Felbamate (marketed as Felbatol)	Pregabalin (marketed as Lyrica)
Gabapentin (marketed as Neurontin)	Tiagabine (marketed as Gabitril)
Lamotrigine (marketed as Lamictal)	Topiramate (marketed as Topamax)
Levetiracetam (marketed as Keppra)	Valproate (marketed as Depakote, Depakote ER, Depakene, Depacon)
Zonisamide (marketed as Zonegran)	

Although the 11 drugs listed above were the ones included in the analysis, FDA expects that the increased risk of suicidality is shared by all antiepileptic drugs and anticipates that the class labeling changes will be applied broadly.

Read the complete 2008 MedWatch Safety Summary including a link to the Healthcare Professional Sheet regarding this issue at:

<http://www.fda.gov/medwatch/safety/2008/safety08.htm#Antiepileptic>
<http://www.fda.gov/cder/drug/infopage/antiepileptics/default.htm>

MedWatch ... (2/1/2008) The announced important **revisions** to the WARNINGS and PRECAUTIONS sections of the prescribing information **for Chantix** regarding serious neuropsychiatric symptoms including changes in behavior, agitation, depressed mood, suicidal ideation, and attempted and completed suicide. In most cases, neuropsychiatric symptoms developed during Chantix treatment, but in others, symptoms developed following its withdrawal. See the FDA Information for Healthcare Professionals Sheet for recommendations and considerations for healthcare professionals on using Chantix therapy for patients. Read the complete 2008 MedWatch Safety Summary including a link to the FDA Public Health Advisory, Healthcare Professional Information Sheet and the prescribing information for Chantix regarding this issue at: <http://www.fda.gov/medwatch/safety/2008/safety08.htm#Varenicline>
<http://www.fda.gov/cder/drug/infopage/varenicline/default.htm>

FROM THE MEDICAL LITERATURE ...

Lifestyle does matter ... A population-based study of 20,244 men and women aged 45-79 with no known cardiovascular disease or cancer at baseline was conducted in the United Kingdom; surveys administered in 1993-1997. Four lifestyle choices were monitored: smoking, physical activity, alcohol intake and fruit/vegetable intake (measured by plasma vitamin C levels). After an average of 11 years of follow up, all-cause mortality was noted in the four groups i.e., those patients who practiced 1, 2, 3, or all 4 healthy behaviors. The group that exhibited all four of the healthy behaviors compared to those practicing none was estimated to be equivalent to 14 years younger. Another way to look at it: you don't smoke, exercise regularly, drink alcohol in moderation and eat at least five servings a day of fruits and vegetables, **you will live 14 years longer** than someone who does not.

Khaw KT, Wareham N, Bingham S, Welch A, Luben R, et al. Combined impact of health behaviours and mortality in men and women: The EPIC-Norfolk prospective population study. *PLoS Med*.

2008;5(1):e12.doi:10.1371/journal.pmed.0050012.

Cough/cold meds in children and emergency department visits ... A national sample of 63 emergency departments was conducted to estimate the admissions due to adverse events caused by cough and cold medications in children for 2 years, between January 1, 2004 and December 31, 2005. An estimated 7091 patients <12 years old were treated in emergency departments (5.7% of total admissions) due to cough and cold medication adverse events; 64% of the visits were by children aged 2 to 5 years. The most common precipitating factor was unsupervised administration, particularly in the 2 to 5 year age group. Dosing error were also common and most in the <2 year old children, where a labeled dose does not exist. Most children (93%) were not admitted or kept for extended observation.



Schaefer MK, Shehab N, Cohen AL, Budnitz DS. Adverse events attributable to cough and cold medications in children. *Pediatrics*. 2008 Jan 28 online; DOI: 10.1542/peds.2007-3638.

<http://pediatrics.aappublications.org/cgi/content/abstract/peds.2007-3638v1>

Costs of diabetes ... was estimated using a prevalence-based approach. Data sources included numerous national surveys detailed in the study. The authors estimate, in 2007, the total cost of diabetes to be \$174 billion (\$116 billion in excess medical expenditures and \$58 billion for reduced productivity (including absenteeism, chronic disability and premature mortality). The average diabetic patient spends \$11,744 per year which is 2.3 times that for a person without diabetes. These costs are rising faster than inflation due primarily to an increased prevalence of diabetes and the increased cost of medical care. The authors also felt they were being conservative with their estimates.

American Diabetes Association. Economic costs of diabetes in the U.S. in 2007. *Diabetes Care*. 2008 Mar;31(3):...

<http://care.diabetesjournals.org/misc/econcosts.pdf>

OTC product ototoxic? ... A very small animal study (5 chinchillas) has called into question the safety of a common OTC product to soften ear wax, Cerumenex[®] (triethanolamine polypeptide). The investigators found that instilling the product in the ear with a perforated tympanic membrane caused hearing loss and damage to the cells of the inner ear. Their concern is the use of the product by patients who would have no way of knowing if their ear drums were compromised and use could permanently damage hearing.



Daniel SJ, Sahmkow SI, Munguia R, Schloss M, Akache F. Ototoxicity of triethanolamine polypeptide (Cerumenex) in the chinchilla. *Laryngoscope*. 2007;118: prepublication.

Reviews of Note ...

- Rucker D, Padwal R, Li SK, Curioni C, Lau DCW. Long term pharmacotherapy for obesity and overweight: Updated meta-analysis. *BMJ*. 2007 Nov 15; doi:10.1136/bmj.39385.413113.25
- Bardia A, Tleyjeh IM, Cerhan JR, Sood AK, Limburg PJ, Erwin PJ, et al. Efficacy of antioxidant supplementation in reducing primary cancer incidence and mortality: Systematic review and meta-analysis. *Mayo Clin Proc*. 2008 Jan;83(1):23-34.
- Moeller KE, Lee KC, Kissack JC. Urine drug screening: Practical guide for clinicians. *Mayo Clin Proc*. 2008 Jan;83(1):66-76.
- Tosh PK, Boyce TG, Poland GA. Flu myths: Dispelling the myths associated with live attenuated influenza vaccine. *Mayo Clin Proc*. 2008 Jan;83(1):77-84.
- Casey PM, Cerhan JR, Pruthi S. Oral contraceptive use and the risk of breast cancer. *Mayo Clin Proc*. 2008 Jan;83(1):86-91.

- Cherry JD. Croup. *N Engl J Med*. 2008 Jan 24;358(4):384-391.
- Correll T, Klibanov OM. Integrase inhibitors: A new treatment option for patients with human immunodeficiency virus infection. *Pharmacotherapy*. 2008 Jan;28(1):90-101.
- Hersh EV, Pinto A, Moore PA. Adverse drug interactions involving common prescription and over-the-counter analgesic agents. *Clin Ther*. 2007;29(Theme):2477-2497.

FROM THE LAY LITERATURE about medicine ...

Morgellons Disease ... Perhaps an old disease described in the 17th century, but one very recently receiving attention. Also known as “fiber disease,” sufferers describe intense itching with crawling/biting/stinging sensations on skin. In addition, fiber-like material (blue, red, green, etc) and sometimes bugs, seems to come out of the skin. There is also a significant component of neurological effects, including delusions or hallucinations. The majority of physicians with experience with these patients put the emphasis on the delusions. A few are predicting a coming epidemic, thinking this may be infectious in nature. The Internet has given a voice to sufferers who otherwise would not know of each other. Stories in the article sound very convincing, yet there is virtually no scientific evidence to back it up.



Schulte B. Figments of the imagination? *Washington Post*. 2008 Jan 20; p. W10.

<http://www.washingtonpost.com/wp-dyn/content/article/2008/01/16/AR2008011603134.html?wpisrc=newsletter>

‘Miffy’ quietly making an impact ... Mifepristone (Mifeprex[®], previously known as RU-486 and now often called ‘Miffy’) was approved for inducing abortions in 2000. A dramatic impact on the number of abortions was expected but did not materialize. However, the number of abortions being performed using mifepristone has increased, more in some locations than others. Perhaps the biggest impact is that it has allowed those seeking abortions to obtain them from a variety of practitioners, not just abortion clinics. This has greatly increased the chance of privacy for the patient (and therefore perhaps its use) since the vocal opponents can no longer target only the specialty clinics. The greatest attraction for this method for patients appears to be that it takes place in their home.

Stein R. As abortion rate drops, use of RU-486 is on rise. *Washington Post*. 2008 Jan 22; p. A01.

<http://www.washingtonpost.com/wp-dyn/content/article/2008/01/21/AR2008012102075.html?wpisrc=newsletter>



The last “dose” ...



Nothing is more honorable than a grateful heart ❤️

~Lucius Annaeus Seneca [4 BC - 65 AD] Roman Stoic
Philosopher

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