

AU InforMed

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Key Inforbits

- New drugs – rufinamide and eltrombopag
- New guidelines for hyperglycemia in DM2
- New guidelines for 2nd gen. antidepressants
- 5 simple life-saving techniques
- Nocebo's
- Happy Thanksgiving

NEW DRUGS, and other related stuff ...

New Drug ... (11/14/2008) The FDA has approved **rufinamide (Banzel™** by Eisai Co, Ltd.) tablets. Rufinamide is indicated for adjunctive treatment of seizures associated with Lennox-Gastaut syndrome in patients ≥ 4 years old. It is contraindicated in patients with Familial Short QT syndrome. More common adverse reactions include somnolence, nausea/vomiting, headache, dizziness, and fatigue. Adult dosing is initiated at 400-800 mg/day, up to a maximum of 3200 mg/day, administered in 2 equal doses. It should be given with food.

<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm> (Drugs@FDA – label available)
www.banzel.com (Manufacturer web site)

New Drug ... (11/20/2008) The FDA has approved **eltrombopag (Promacta®** by GlaxoSmithKline) for the treatment of thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who have had an insufficient response to other therapies. It is an oral thrombopoietin receptor agonist. Also, prescribers and pharmacies must enroll in Promacta® *Cares* before they can prescribe or dispense eltrombopag. Similarly, patients are required to enroll in Promacta® *Cares* before they can receive the drug. This program was created in accordance with the FDA's requirements to help assure the appropriate and safe use of eltrombopag, while minimizing risks, including the risk of hepatotoxicity. Promacta® *Cares* is part of an ongoing collaboration between GSK and the FDA to provide a format for appropriate additional data collection.

http://www.gsk.com/media/pressreleases/2008/2008_pressrelease_10127.htm (GSK Press Release)

MedWatch ... (11/10/2008) Ethex Corp and the FDA have announced a **voluntary recall of five generic products** (Propafenone HCl Tablets, Isosorbide Mononitrate Extended Release Tablets, Morphine Sulfate Extended Release Tablets, Morphine Sulfate Immediate Release Tablets, and Dextroamphetamine Sulfate Tablets). The products were recalled because they may include oversized tablets that may contain more than the intended levels of the active drug ingredient. This could result in patients receiving as much as twice the expected dosage of these drugs. Patients who experience any adverse reactions to these drugs should contact their healthcare professional immediately. See the manufacturer's recall notice for specific lot numbers of the products affected by this recall.

Read the entire MedWatch 2008 Safety Summary, including a link to the manufacturer's recall notice regarding the above issue at:

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

MedWatch ... (11/12/2008) Johnson & Johnson- Merck Consumer Pharmaceuticals Company and the FDA announced a **voluntary recall of Infants' Mylicon Gas Relief Dye Free Drops** (Lot No. SMF007 and SMF008) sold in 1 oz plastic bottles that were distributed nationwide after October 5, 2008. The product was recalled because some bottles could include metal fragments that were generated during the manufacturing process. Parents who have given the product to their infant and are concerned should contact their healthcare professional.

Read the entire 2008 MedWatch Safety Summary, including a link to the manufacturer's recall notice regarding the above issue at:

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

MedWatch ... (11/12/2008) The FDA issued an update about the Agency's review of safety data regarding the potential increased risk of **atrial fibrillation in patients treated with a bisphosphonate drug**. The FDA reviewed data on 19,687 bisphosphonate-treated patients and 18,358 placebo-treated patients who were followed for 6 months to 3 years. The occurrence of atrial fibrillation was rare within each study, with most studies containing 2 or fewer events. No clear association between overall bisphosphonate exposure and the rate of serious or non-serious atrial fibrillation was observed. Also, increasing dose or duration of bisphosphonate therapy was not associated with increased atrial fibrillation. Healthcare professionals should not alter their prescribing patterns for bisphosphonates and patients should not stop taking their bisphosphonate medication. Bisphosphonates are marketed as Alendronate (Fosamax[®], Fosamax Plus D[®]); Etidronate (Didronel[®]); Ibandronate (Boniva[®]); Pamidronate (Aredia[®]); Risedronate (Actonel[®], Actonel W/Calcium[®]); Tiludronate (Skelid[®]); Zoledronic acid (Reclast[®], Zometa[®]).

Read the entire 2008 MedWatch Safety Summary, including a link to the FDA Update of Safety Review Follow-up to the October 1, 2007, Early Communication about the Ongoing Safety Review of Bisphosphonates, regarding this issue at:

<http://www.fda.gov/medwatch/safety/2008/safety08.htm#bisphosphonates2>

MedWatch ... (11/18/2008) CSI USA Inc. and the FDA announced a **nationwide recall of all lots of 1 ounce tubes of 10% Benzoyl Peroxide Acne Cream** marked as: DG Maximum Strength Acne Medicated Gel; Kroger Acne Gel 10% Benzoyl Peroxide Acne Medication; Equate: Medicated Acne Gel. Samples of the products were found to contain bacteria, *Burkholderia Cepacia*, formerly known as *Pseudomonas Cepacia*. There may be an increased health risk of infections for individuals with cuts, scrapes, rashes or other compromised skin conditions; or those with weakened or suppressed immune systems. Consumers should discontinue using the product and should return it to the place of purchase.

Read the entire 2008 MedWatch Safety Summary, including a link to the manufacturer's recall press release at: <http://www.fda.gov/medwatch/safety/2008/safety08.htm#Benzoyl>

FROM THE MEDICAL LITERATURE ...

History of Big Pharma and Medical Education ... A brief history of the beginnings of the



pharmaceutical industries influence over medical education and how it evolved. For those interested, a worthy read. This phenomenon is not recent and has its beginnings with the 'wonder drugs' development in the 1950's. Many of the arguments from medical academia back then are still being voiced today.

Podolsky SH, Greene JA. A historical perspective of pharmaceutical promotion and physician education. JAMA. 2008 Aug 20;300(7):831-833.

Hyperglycemia management in DM2 guidelines ... A consensus statement of the American Diabetes Association and the European Association for the Study of Diabetes produced an algorithm for the medical management of type 2 diabetes in August of 2006. This algorithm has been updated to focus on newer classes of drugs. It emphasizes achievement of A1C < 7.0%; initial changes of lifestyle + metformin; rapid additions of other medications to achieve goals; and early addition of insulin therapy for patients not meeting targets.



Nathan DM, Buse JB, Davidson MB, Ferrannini E, Holman RR, Sherwin R, Zinman B. Medical management of hyperglycemia in type 2 diabetes: A consensus algorithm for the initiation and adjustment of therapy. *Diabetes Care*. 2008 Dec;31(12):1-11.

2nd Generation Antidepressants – Guidelines ... Guidelines for the use of second generation antidepressants have been issued by the American College of Physicians (ACP). After review of over 200 studies, the data did not allow for a relative assessment of these agents based on efficacy. However, the ACP presented four recommendations based on their evidence-based literature review, paraphrased here: 1) Selection of 2nd generation antidepressants should be based on adverse effect profiles, cost and patient preferences. 2) Assessments of patient status, therapeutic response and adverse effects should be done regularly, beginning within 1-2 weeks of therapy initiation. 3) If response is inadequate, therapy modification should take place within 6-8 weeks for major depressive disorder. 4) For a first episode of major depressive disorder, therapy should continue for 4-9 months after satisfactory response. Therapy should be continued longer if patient has had 2 or more such episodes. Now you know.



Qaseem A, Snow V, Denberg TD, Forciea MA, Owens DK, for the Clinical Efficacy Assessment Subcommittee of the American College of Physicians. *Ann Intern Med*. 2008;149:725-733.

Gartlehner G, Gaynes BN, Hansen RA, Thieda P, DeVeugh-Geiss A, Krebs EE, Moore CG, Morgan L, Lohr KN. Comparative benefits and harms of second-generation antidepressants: Background paper for the American College of Physicians. *Ann Intern Med*. 2008;149:734-750.

Reviews of Note ...

- Baldwin CM, Scott LJ. Mometasone furoate: A review of its intranasal use in allergic rhinitis. *Drugs*. 2008;68(12):1723-1739.
- Deeks ED, Perry CM. Ciclesonide: A review of its use in the management of asthma. *Drugs*. 2008;68(12):1741-1770.
- Anton RF. Naltrexone for the management of alcohol dependence. *N Engl J Med*. 2008 Aug 14;359(7):715-721.
- Kumar R. Approved and investigational uses of modafinil: An evidence-based review. *Drugs*. 2008;68(13):1803-1839.
- Simpson D, Curran MP. Ramelteon: A review of its use in insomnia. *Drugs*. 2008;68(13):1901-1919.
- Furie B, Furie BC. Mechanism of thrombus formation. *N Engl J Med*. 2008 Aug 28;359(9):938-949.

FROM THE LAY LITERATURE about medicine ...

5 Simple Ways to Save a Life ... Interesting choices and most of them are “don’ts”

- Don’t remove a foreign object (especially large things that someone has been accidentally impaled with)

- Don't apply a tourniquet to stop bleeding, but do apply pressure.
- Do ask around for an Epi-Pen if someone is having a severe allergic reaction
- Don't clean a tooth that has fallen out (put it in milk and go to the ER)
- Don't move someone who has fallen from a high place



and in most of these cases, call 911!

Cohen E. Five simple ways to save a life. CNN.com 2008 Sep 4.

<http://www.cnn.com/2008/HEALTH/09/04/ep.first.aid/index.html>

Vocabulary ... Nocebos ... is roughly defined as the expectation of becoming ill due to some known or perceived exposure to risk factors or developing a side effect from a drug because of knowledge of its potential to cause such. As this article put it, "placebo's evil twin." Numerous examples are cited of its occurrence and it is a common fear among pharmacists that providing too much information to patients about possible adverse effects may stimulate their development. Much of it relates to how individual patients process such information so suffice it to say, it happens and it's up to the practitioner on what is the best way to manage it.

Beck M. Power of suggestion: When drug labels make you sick. Wall Street Journal. 2008 Nov 18.

<http://online.wsj.com/article/SB122696995090235703.html?mod=djemHL> (subscription only)

NEW RESOURCES in the DILRC ...

- Shrewsbury R. Applied Pharmaceutics in Contemporary Compounding. 2nd ed. Englewood, CO: Morton, 2008.
- DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey LM, eds. Pharmacotherapy: A Pathophysiologic Approach. 7th ed. NY: McGraw-Hill, 2008.
- Gulseth M. *Managing Anticoagulation Patients in the Hospital: The Inpatient Anticoagulation Service*. Bethesda, MD: American Society of Health System Pharmacists, 2007.
- Ginsburg DB. *ASHP's PharmPrep: Interactive Case-Based Board Review*. 3rd ed. Bethesda, MD: American Society of Health System Pharmacists, 2006.
- Desai A, Lee M. *Gibaldi's Drug Delivery Systems in Pharmaceutical Care*. Bethesda, MD: American Society of Health System Pharmacists, 2007.



The last "dose" ...

Let us remember that, as much has been given us, much will be expected from us, and that true homage comes from the heart as well as from the lips, and shows itself in deeds.



... Theodore Roosevelt (1858 - 1919)



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