

AU InforMed

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Key Inforbits

- New dose form for a NSAID
- Many, many **MedWatches**
- History of OTC drug regulation, Woo Hoo!
- Fake drugs worldwide!
- Drug interactions according to the NY Times
- Horrible life

NEW DRUGS, and other related stuff ...

New Dose Form ... diclofenac epolamine topical patch (**Flector[®] Patch** by Institut Biochimique SA) was approved for the U.S. market by the FDA on January 31, 2007. It is intended to provide local pain relief for minor strains, sprains, and contusions. It is applied twice daily to intact skin only. It should not be worn when bathing or showering. The label and approval letter are at drugs@fda.gov

MedWatch ... (2/16/2007) The FDA notified healthcare professionals of the results from a large clinical trial evaluating use of an erythropoiesis-stimulating agent (ESA) to treat anemia in **cancer patients not receiving chemotherapy**. In this study, patients received either Aranesp, an ESA, according to the approved dosing regimen or placebo. **Patients treated with Aranesp had a higher death rate** and no reduction in the need for transfusions compared to those treated with placebo. The findings in the Aranesp study may apply to other ESAs. Additionally, the findings show that treating anemic cancer patients not currently on chemotherapy with an ESA may offer no benefit and may cause serious harm.

Read the complete MedWatch 2007 Safety summary, including links to the FDA Information For Healthcare Professionals Sheet and previous MedWatch alerts regarding this issue at: <http://www.fda.gov/medwatch/safety/2007/safety07.htm#ESA>

MedWatch ... (2/16/2007) The FDA informed consumers and healthcare professionals regarding the possible **dangers of buying prescription medications online**. Individuals who ordered Ambien, Xanax, Lexapro, and Ativan over the internet received a product that contained haloperidol, a powerful anti-psychotic drug. Several consumers experienced difficulty in breathing, muscle spasms and muscle stiffness after ingesting the suspect product and had to seek emergency medical treatment. Haloperidol can cause muscle stiffness, spasms, agitation and sedation. Taking medication that contains an active ingredient other than what is prescribed by qualified healthcare professionals is generally unsafe. FDA urges consumers to review the FDA website for additional information prior to making purchases of medications over the internet (<http://www.fda.gov/buyonline/>).

Read the complete MedWatch 2007 Safety summary, including links to the FDA Press Release regarding this issue at:

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

MedWatch ... (2/20/2007) Glaxo SmithKline (GSK) notified healthcare professionals of the results of a randomized, double-blind parallel group study [ADOPT] of 4,360 patients with recently diagnosed type 2 diabetes mellitus followed for 4-6 years to compare glycemic control with rosiglitazone relative to metformin and glyburide monotherapies. Significantly **more female patients who received rosiglitazone experienced fractures of the upper arm, hand, or foot**, than did female patients who received either metformin or glyburide. At GSK's request, an independent safety committee reviewed an interim analysis of fractures in another large, ongoing, controlled clinical trial and preliminary analysis was reported as being consistent with the observations from ADOPT. Healthcare professionals should consider the risk of fracture when initiating or treating female patients with type 2 diabetes mellitus with rosiglitazone. Read the complete MedWatch 2007 Safety summary, including a link to the GSK Dear Healthcare Professional letter, at:

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

MedWatch ... (2/21/2007). The FDA notified asthmatic patients and healthcare professionals of new reports of **serious and life-threatening allergic reactions (anaphylaxis) in patients after treatment with Xolair**. Usually these reactions occur within two hours of receiving a Xolair subcutaneous injection. However, these new reports include patients who had delayed anaphylaxis (with onset two to 24 hours or even longer) after receiving Xolair treatment. Anaphylaxis may occur after any dose of Xolair (including the first dose), even if the patient had no allergic reaction to the first dose. Health care professionals who administer Xolair should be prepared to manage life-threatening anaphylaxis and should observe their Xolair-treated patients for at least two hours after Xolair is given. Patients under treatment with Xolair should be fully informed about the signs and symptoms of anaphylaxis, their chance of developing delayed anaphylaxis following Xolair treatment, and how to treat it when it occurs. FDA has requested Genentech add a boxed warning to the product label and to revise the label and provide a Medication Guide for patients.

Read the complete MedWatch 2007 Safety summary, including links to the Healthcare Professional information sheet and FDA press statement, at:

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

MedWatch ... The FDA notified healthcare professionals that the manufacturers of all drug products approved for the treatment of **Attention Deficit Hyperactivity Disorder (ADHD)** have been directed to develop **Patient Medication Guides** to alert patients to possible cardiovascular risks and risks of adverse psychiatric symptoms associated with the medicines and to advise them of precautions that can be taken. Patient Medication Guides are handouts given to patients, families and caregivers each time a medicine is dispensed. The guides contain FDA-approved patient information that could help prevent serious adverse events. An FDA review of reports of serious cardiovascular adverse events in patients taking usual doses of ADHD products revealed reports of sudden death in patients with underlying serious heart problems or defects, and reports of stroke and heart attack in adults with certain risk factors. FDA recommends that children, adolescents, or adults who are being considered for treatment with ADHD drug products work with their physician or other health care professional to develop a treatment plan.

Read the complete MedWatch 2007 Safety summary, including links to the draft version of the Medication Guides and the FDA press statement, at:

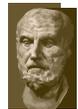
<http://www.fda.gov/medwatch/safety/2007/safety07.htm#ADHD>

MedWatch ... (2/22/2007) Roche and the FDA notified cardiac transplant healthcare practitioners about a **clinical study** (Heart Spare The Nephron) that was **terminated due to an observed increased incidence of grade IIIA acute rejection in heart transplant patients switched from calcineurin inhibitor and CellCept to Rapamune (sirolimus) and CellCept at 12 weeks post heart transplantation**. The safety and efficacy of CellCept in combination with sirolimus following withdrawal of initial calcineurin inhibitor therapy has not been established. Read the complete MedWatch 2007 Safety summary, including a link to the Roche Dear Healthcare Professional letter, at:
<http://www.fda.gov/medwatch/safety/2007/safety07.htm#CellCept>

MedWatch ... (2/24/2007). The FDA and Bristol-Myers Squibb announced revisions to the MICROBIOLOGY/Antiviral Activity and INDICATIONS AND USAGE/Description of Clinical Studies/Special Populations sections of the prescribing information for Baraclude. The revised labeling is the result of a case report in which a **human immunodeficiency virus (HIV) variant containing the M184V resistance substitution was documented during Baraclude treatment** for chronic hepatitis B virus (HBV) infection in an HIV/HBV co-infected patient who was not simultaneously receiving highly active antiretroviral therapy (HAART). Current treatment guidelines recommend Baraclude as an option for treatment of HBV in the HIV/HBV co-infected adult patient who does not qualify for HAART. Healthcare professionals are advised that when considering therapy with Baraclude in an HIV/HBV co-infected patient not receiving HAART, the risk of developing HIV resistance cannot be excluded based on current information. Read the complete MedWatch 2007 Safety summary, including links to the Manufacturer's Dear Healthcare Provider Letter and revised labeling, at:
<http://www.fda.gov/medwatch/safety/2007/safety07.htm#Baraclude>

FROM THE MEDICAL LITERATURE ...

OTC history ... The FDA has released a new web site that has collated the rule-making history of nonprescription drug products. It is divided into alphabetical categories. There is a disclaimer that the site is not guaranteed of being completely accurate, but for those who are interested in historical developments of OTCs, it should be an invaluable resource. FDA. Rulemaking History for Nonprescription Products: Drug Category List. 2007 Feb 23.



http://www.fda.gov/cder/otcmonographs/rulemaking_index.htm

Reviews of Note ...

- Scott JD, Gretch DR. Molecular diagnostics of hepatitis C virus infection: A systematic review. *JAMA*. 2007 Feb 21;297(7):724-32.
- Camilleri M. Diabetic gastroparesis. *N Engl J Med*. 2007 Feb 22;356(8):820-829.

FROM THE LAY LITERATURE about medicine ...

Fake drugs – worse in the third world ... As in the FDA report above from MedWatch, counterfeit drugs are a world-wide scourge. A recent article has shed some light on a global, deadly problem. As opposed to the common counterfeits in the U.S. (eg, sleep aids, narcotics, sildenafil), one of the main problems in other parts of the world are malaria drugs. Manufacturers of fake drugs such as artemisinin are sophisticated enough to produce identical

looking tablets, down to the packaging and holograms. It can mean a death sentence to untold numbers either because of succumbing to the disease (fakes) or the development of resistance (low potency).

McNeil DG. In the world of life-saving drugs, a growing epidemic of deadly fakes. *New York Times*. 2007 Feb 20.



http://www.nytimes.com/2007/02/20/science/20coun.html?_r=1&oref=slogin&ref=health&page_wanted=print

Free drugs – only part of the story ... It seems that some big employers are finally catching on to the rationale of wellness care. Faced with rapidly rising insurance costs some companies are giving away free drugs. These are drugs for chronic diseases such as hypertension, diabetes, and asthma that are available generically; by increasing medication compliance by waiving co-pays, money is saved from avoiding emergency room visits and hospitalizations due to worsening disease or exacerbations. As a hidden **pearl** of the article, pharmacists are mentioned several times as being integral to this process in the role of pharmaceutical care, patient monitoring and promotion of wellness.



Freudenheim M. Some employers are offering free drugs. *New York Times*. 2007 Feb 21.

<http://www.nytimes.com/2007/02/21/business/21free.html?ref=health>

Drug interactions, oh my ... A news article centering on the dangers of drug interactions. It draws most of its information from a *JAMA* article last fall and the most recent Institute of Medicine (IOM) report last summer. It also cites some statistics about the number of prescriptions, over-the-counter medications  and herbals taken by the U.S. population and some of their dangers - nothing too new or exciting. However, accompanying the article is a .pdf file showing many of the more severe potential interactions in a single, complex diagram. It may be worth taking a look, if for nothing else reducing a lot of information to a single picture.

Markel H. How two rights can make a wrong. *New York Times*. 2007 Feb 25.

<http://www.nytimes.com/2007/02/24/weekinreview/25markel.html?ref=health>

Update ...

Student Pharmacist edition ... of *U.S. Pharmacist* (Spring 2007) is available in the DIC; free issues for the taking. Main topics are academic career options and some of the why's and wherefore's concerning employment background checks.



The last “dose” ...

“To live by medicine is to live horribly.”

--Linnaeus [Carl von Linné] (1707-1778),
Diaeta Naturalis, introduction

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