

AU InforMed

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Key Inforbits

- New drug, new dose form, new generic
- Birth rates in the U.S. and in Alabama
- Smoking-related mortality in the U.S./Alabama
- “Automatic” ADR reporting coming
- Sleeping aids becoming more popular
- Happy Groundhog day!

NEW DRUGS, and other related stuff ...

New Drug ... (1/16/2009) The FDA has licensed RiaSTAP (CSL Behring, Marburg, Germany), an orphan drug for the treatment of bleeding in patients with a rare genetic defect, congenital fibrinogen deficiency. **RiaSTAP is an intravenous fibrinogen concentrate** made from the plasma of healthy human blood donors. The product is indicated for patients who have afibrinogenemia, or for those patients whose fibrinogen levels are below 50 mg/dL (hypofibrinogenemia). It is not indicated for patients with dysfibrinogenemia, who may have normal fibrinogen levels but defective fibrinogen function. People with congenital fibrinogen deficiency are unable to make sufficient amounts of fibrinogen, which plays an important role in blood coagulation by helping to form blood clots and prevent bleeding. Fibrinogen deficiency affects only 150 to 300 people in the U.S. and is usually diagnosed at birth.

<http://www.fda.gov/bbs/topics/NEWS/2009/NEW01948.html> (FDA News release)

<http://www.riastap.com/> (Manufacturer site with complete prescribing information)

New Dose Form ... (1/27/2009) The FDA has approved **Gelnique™ (oxybutynin chloride) Gel 10%**, for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and frequency. Because oxybutynin, an antispasmodic agent, is delivered transdermally, it is not metabolized by the liver in the same way as orally administered oxybutynin resulting in fewer side effects, such as dry mouth and constipation. Watson anticipates that the product will be available to patients in the second quarter of 2009. Gelnique™ is a quick-drying, clear and colorless, fragrance-free hydroalcoholic gel. It is applied once daily and delivers a consistent dose of oxybutynin through the skin over a 24-hour period. The most frequently reported adverse events were dry mouth (6.9%) and application-site reactions (5.4%). In addition, showering one hour or later, or the application of sunscreen 30 minutes before or after Gelnique™ application did not significantly alter drug absorption.

www.gelnique.com (Complete prescribing information)

<http://www.gelnique.com/news.asp> (Manufacturer press release)

New Generic ... (1/23/2009) Mylan Pharmaceuticals Inc. received final approval from the FDA for its supplemental Abbreviated New Drug Application (ANDA) for **Omeprazole Delayed-release (DR) Capsules USP, 40 mg**, the generic version of AstraZeneca's Prilosec® DR Capsules. Omeprazole DR Capsules are indicated for the treatment of peptic ulcers and gastroesophageal reflux disease (GERD). Mylan is shipping this product immediately.

<http://investor.mylan.com/phoenix.zhtml?c=66563&p=irol-newsArticle&ID=1247648&highlight=>

MedWatch ... (1/26/2009) The FDA announced that the makers of Plavix[®] have agreed to conduct studies to allow a better understanding and characterization of the effects of genetic factors and other drugs (especially the proton pump inhibitors (PPIs)) on the **effectiveness of clopidogrel**. FDA is aware of published reports that clopidogrel is less effective in some patients than it is in others. Differences in effectiveness may be due to genetic differences in the way the body metabolizes clopidogrel or that using certain other drugs with clopidogrel can interfere with how the body metabolizes clopidogrel. The drug manufacturers have agreed to a timeline for completing the studies and FDA will review the new information expeditiously and will communicate its conclusions and any recommendations to the public at that time. It could take several months to complete the studies and analyze the results. Until further information is available FDA recommends the following:

- * Healthcare providers should continue to prescribe and patients should continue to take clopidogrel as directed, because clopidogrel has demonstrated benefits in preventing blood clots that could lead to a heart attack or stroke.

- * Healthcare providers should re-evaluate the need for starting or continuing treatment with a PPI, including Prilosec[®] OTC, in patients taking clopidogrel.

- * Patients taking clopidogrel should consult with their healthcare provider if they are currently taking or considering taking a PPI, including Prilosec[®] OTC.

Read the complete MedWatch 2009 Safety summary, including a link to the Early

Communication, at: <http://www.fda.gov/medwatch/safety/2009/safety09.htm#plavix>

MedWatch ... (1/27/2009) **The FDA notified consumers not to take Venom HYPERDRIVE 3.0**, a product sold as a dietary supplement but containing sibutramine, an undeclared drug product and a controlled substance with risks for abuse or addiction. When present in a dietary supplement, it may harm unsuspecting consumers because sibutramine can substantially increase blood pressure and heart rate, and may present a significant risk for people with a history of heart disease, heart failure, irregular heart beats or stroke. The product was sold nationwide and was packaged in red plastic bottles containing 90 capsules each with the UPC# 094922534743. Consumers who have this product should stop taking it immediately and contact their health care professional if they have experienced any adverse effects.

Read the MedWatch 2009 safety summary, including a link to the FDA News Release, at:

<http://www.fda.gov/medwatch/safety/2009/safety09.htm#Venom>

MedWatch ... (1/28/2009) The FDA notified pharmacists and consumers that ETHEX Corporation has expanded two previous 2008 **recalls to include over 60 generic drug products** recalled to wholesalers, and two generic drug products, hydromorphone HCl and metoprolol succinate, recalled to retailer level. These generic products may have been manufactured under conditions that did not sufficiently comply with current Good Manufacturing Practices. Some of these products have had specific lots recalled earlier due to defects found, including oversized tablets delivering higher than labeled doses. Patients who may have these medicines should continue to take them in accordance with their prescriptions, as the risk of suddenly stopping needed medication may place patients at risk. Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to using these products, or to obtain replacement medications or prescriptions.

Read the complete MedWatch 2009 Safety summary, including links to the firm's press release and two previous alerts, at: <http://www.fda.gov/medwatch/safety/2009/safety09.htm#Ethex>

FROM THE MEDICAL LITERATURE ...

Birth Rates in the U.S. ... The latest information on birth data in the U.S. is from 2006 and was just released in a 102 page report from the National Vital Statistics Reports. Much of the data centered on teenage pregnancies and births and the racial/ethnic background of the mothers. This report's data was broadcast nationally and covered only the top 10 states for teenage births; Mississippi was tops in the land for this dubious distinction. The good news for **Alabama** is we were not in the top 10; the bad news is we were number 12. If you like lots of numbers and trends, this will put you in heaven.



Rothwell CJ, Dir. Births: Final data for 2006. National Vital Statistics Reports. 2009 Jan 6;57(7):1-102.

http://www.cdc.gov/nchs/data/nvsr/nvsr57/nvsr57_07.pdf

Smoking-attributed mortality is down ... Smoking can cause lung and other cancers, coronary heart disease, stroke, chronic respiratory disease, and other diseases. In 2008, the CDC reported that cigarette smoking and exposure to secondhand smoke resulted in an estimated 443,000 deaths and 5.1 million years of potential life lost (YPLL) annually in the United States during 2000-2004. A new report presents state-specific average annual smoking-attributable mortality (SAM) and YPLL estimates for the same period among adults aged ≥ 35 years. The report also compares 2000-2004 average annual SAM rates per 100,000 population with rates for 1996-1999. For **Alabama**, the good news is that in comparing the two time periods (1996-1999 vs. 2000-2004) the SAM dropped 5.9%. The bad news is that only one state did worse, Kansas, and Alabama was much worse than the 50-state average of 24.8%. State-specific smoking-attributable mortality and years of potential life lost-United States, 2000-2004. MMWR. 2009 Jan 23; 58(02):29-33.



<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5802a2.htm>

Reviews of Note ...

- Abramowicz M, ed. Drugs that may cause psychiatric symptoms. *Med Lett Drugs Ther.* 2008 Dec 15/29;50(1301/1302):100-104.
- Verdu B, Decosterd I, Buclin T, Stiefel F, Berney A. Antidepressants for the treatment of chronic pain. *Drugs.* 2008;68(18):2611-2632.
- Lyseng-Williamson KA. Zoledronic acid: A review of its use in breast cancer. *Drugs.* 2008;68(18):2661-2682.
- Frampton JE, Perry CM. Ibandronate: A review of its use in the management of postmenopausal osteoporosis. *Drugs.* 2008;68(18):2683-2707.
- Blick SKA, Dhillon S, Keam SJ. Teriparatide: A review of its use in osteoporosis. *Drugs.* 2008;68(18):2709-2737.

FROM THE LAY LITERATURE about medicine ...

ADR reporting part of the EMR ... A new project is being partially funded by the pharmaceutical industry is making it easier to report adverse drug reactions (ADRs). A form is being incorporated into the electronic medical record (EMR) so that when a physician identifies that a drug is being discontinued or changed due to an ADR, a window pops up. It is very short and quick to fill out (a big complaint about the MedWatch form) and it then is downloaded to a separate entity where it may make it to the federal database. It is only a pilot project in a few hospitals, but if expanded, may have a huge impact on ADR reporting which has historically recorded only a small fraction of actual events. In addition to



goodwill, the drug companies are also fulfilling a mandate for better post-marketing surveillance of approved drugs.

Rockoff JD. Pfizer project looks at side effects: Boston hospitals to use electronic records to encourage doctor reporting. Wall Street Journal. January 2, 2009.

<http://online.wsj.com/article/SB123085142405347511.html?mod=djemHL> (subscription only)

Herbal sales growing ... A bright spot for the economy is the sales of herbal medicines. In the last quarter of 2008 they have increased about 6%; the larger category including vitamins and minerals increased 10% from the 4th quarter of 2007. In 2007 sales of herbal and botanical supplements totaled \$4.8 billion; approximately 18% of Americans consume such products. Unfortunately, this reflects at least in part, the tanking economy and people are turning more to self medication/treatment rather than the more expensive option (at least in the short term) of physicians, prescriptions, etc. This can provide opportunity for pharmacists to guide their patients, and to be sure to ask about supplements for purposes of drug interaction screening.

Tanner L (AP writer). With economy sour, consumers sweet on herbal meds. Chicago Tribune. January 13, 2009.

<http://www.chicagotribune.com/news/chi-ap-meltdown-supplement-s,0,4712010.story>

Sleeping pill use popular in young age group ... This may be surprising to teachers who often have sleeping students in their classes. A study was conducted on data from prescription claims from several large employers from 1998 to 2006. While the most common users are aged 35 to 44 years, their use increased 30% over that time period. The youngest adults, aged 18 to 24 years, increased their use of these medications 3-fold over the 8 years and the next age category of 25 to 34 years saw a doubling of use. Some of the troubling trends include that it seems to show a continuing reliance on medication for problems (the “Ritalin” generation?) and that about 90% of prescriptions were written without involvement of a mental health professional. Does anyone question the effectiveness of drug industry marketing?

Rabin RC. Sleeping pills rising in popularity among young adults. New York Times. January 15, 2009.

http://www.nytimes.com/2009/01/15/health/15sleep.html?_r=1&scp=1&sq=%2b%22mental+health%22+%2bdisorder&st=nyt

NEW RESOURCES in the DILRC ...

- Taketomo CK, Hodding JH, Kraus DM. Pediatric Dosage Handbook. 15th ed. Hudson, OH: Lexi-Comp, Inc, 2008.
- Semla TP, Beizer JL, Hibgbee MD. Geriatric Dosage Handbook. 13th ed. Hudson, OH: Lexi-Comp, Inc, 2008.



The last “dose” ...

The groundhog is like most other prophets; it delivers its prediction and then disappears.

~Bill Vaughn [1915 - 1977] American author and columnist



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