

AU InforMed

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Key Inforbits

- TWO new drugs
- Many MedWatches
- Pharmaceutical Trash
- Pharmacist salary survey released
- National P&T Committee?
- The Mechanic

NEW DRUGS, and other related stuff ...

New Drug ... The FDA approved **lisdexamfetamine dimesylate (Vyvanse™** by New River Pharmaceuticals and Shire) on February 23, 2007. Lisdexamfetamine is a prodrug for dextroamphetamine and it is indicated for the treatment of Attention-Deficit/Hyperactivity Disorder. It comes as 30 mg, 50 mg, and 70 mg capsules and is dosed once daily. Labeling also includes a Medication Guide.

drugs@fda.org (package label)

<http://www.shireadhd treatments.com/> (Shire web site and press release)

New Drug ... The FDA approved aliskiren (Tekturna™ by Novartis Pharmaceuticals Corp) tablets for the treatment of hypertension, on March 6, 2007. Aliskiren is the first hypertension drug approved by the FDA that inhibits renin, thus acts at the beginning of the blood pressure regulation process. The effect was maintained for up to one year. Aliskiren was effective across all demographic subgroups, but African American patients tended to have smaller reductions in blood pressure than Caucasians and Asians, as is generally true for drugs that affect the renin-angiotensin system. Aliskiren was evaluated for safety in more than 6,460 patients. Side effects were usually mild and brief. The most common side effect experienced was diarrhea, reported by approximately 2 percent of patients on the higher of the two approved doses, compared with approximately 1 percent on placebo. Rarely, patients taking aliskiren developed an allergic reaction with swelling of the face, lips or tongue and difficulty breathing, as has been seen with other drugs for high blood pressure that act directly on the renin-angiotensin system. Also, such drugs should not be used during pregnancy because they can cause injury and even death to the developing fetus.

FDA approves new drug treatment for high blood pressure. *FDA News*. 2007 Mar 6; P07-38.

<http://www.fda.gov/bbs/topics/NEWS/2007/NEW01580.html>

New Indication ... The FDA on February 27, 2007, approved **adalimumab (Humira®** by Abbott Laboratories) to treat adult patients with moderately to severely active **Crohn's disease**, a chronic inflammatory disease of the intestines, which affects an estimated one million Americans. Humira® acts to reduce excessive levels of human tumor necrosis factor (TNF) alpha, which plays an important role in abnormal inflammatory and immune responses. The product has been studied in 1,478 patients with Crohn's disease in four clinical trials comparing the drug to a placebo and two longer term extension studies. The labeling of Humira® includes a boxed warning concerning serious, sometimes fatal, infections, including

cases of tuberculosis, opportunistic infections, and sepsis. Other serious adverse events reported include lymphoma, a type of cancer. The most frequent adverse events included upper respiratory infections, sinusitis, and nausea. Humira requires subcutaneous injections (under the skin) to initiate treatment for Crohn's disease, and maintenance treatment is administered as one injection every other week.

FDA Approves new treatment for Crohn's disease. *FDA News* 2007 Feb 27; P07-30.

<http://www.fda.gov/bbs/topics/NEWS/2007/NEW01572.html>

MedWatch ... (3/5/2007). The Gebauer Company notified healthcare professionals and consumers of a **nationwide recall of certain lots of Salivart Oral Moisturizer**. The recall was initiated because some lots do not meet the Company's internal specification for aerobic microorganisms and mold. Use of the affected units may cause temporary and reversible health problems such as nausea, vomiting, and diarrhea. Customers who have the recalled product should stop using the product and dispose of it immediately. See the attached Manufacturer's recall notice for specific lot numbers and expiration dates of the recalled product.

Read the complete MedWatch 2007 Safety Summary, including links to the Manufacturer's Recall notice regarding this issue at:

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

MedWatch ... (3/9/2007). Takeda and FDA notified healthcare professionals of **recent safety data concerning pioglitazone-containing products**. The results of an analysis of the manufacturer's clinical trial database of pioglitazone showed more reports of fractures in female patients taking pioglitazone than those taking a comparator (either placebo or active). The majority of fractures observed in female patients were in the distal upper limb (forearm, hand and wrist) or distal lower limb (foot, ankle, fibula and tibia). There were more than 8100 patients in the pioglitazone-treated groups and over 7400 patients in the comparator-treated groups. The duration of pioglitazone treatment was up to 3.5 years. Healthcare professionals should consider the risk of fracture when initiating or treating female patients with type 2 diabetes mellitus with pioglitazone-containing products.

Read the complete MedWatch 2007 Safety summary, including links to the Manufacturer's Dear Healthcare Provider Letter regarding this issue at:

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

MedWatch ... (3/9/2007). The FDA notified healthcare professionals of **new safety information for erythropoiesis-stimulating agents (ESAs)** Aranesp (darbepoetin alfa), Epogen (epoetin alfa), and Procrit (epoetin alfa). Four new studies in patients with cancer found a higher chance of serious and life-threatening side effects or death with the use of ESAs. These research studies were evaluating an unapproved dosing regimen, a patient population for which ESAs are not approved, or a new unapproved ESA. FDA believes these new concerns apply to all ESAs and is re-evaluating how to safely use this product class. FDA and Amgen, the manufacturer of Aranesp, Epogen and Procrit, have changed the full prescribing information for these drugs to include a new boxed warning, updated warnings, and a change to the dosage and administration sections for all ESAs.

Read the complete MedWatch 2007 Safety summary, including links to the Public Health Advisory, Q and A's, and updated healthcare professional information sheet, at:

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

MedWatch ... The FDA notified healthcare professionals of the **early termination of the INSPIRE clinical study of Actimmune for idiopathic pulmonary fibrosis (IPF)**. The study was stopped because an interim analysis showed that patients with IPF who received Actimmune did not benefit. The trial compared survival in patients getting Actimmune or an inactive injection (placebo). An analysis showed that 14.5% of patients treated with Actimmune died as compared to 12.7% of patients treated with placebo. Actimmune is not approved by the FDA to treat IPF.

Read the complete MedWatch 2007 Safety summary, including a link to the Public Health Advisory and Drug Information Page, at:

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

FROM THE MEDICAL LITERATURE ...

Vancomycin-induced thrombocytopenia ... Collected over five years, 29 patients receiving vancomycin and developing thrombocytopenia, were investigated for the development of specific, vancomycin antibodies. All 29 patients had developed the antibodies, while 25 other patients also receiving vancomycin but not developing thrombocytopenia, did not have antibodies. Some specific features were noted: About 33% of patients had extensive ecchymoses and hemorrhage (“wet purpura”); platelet transfusions failed to elevate platelet levels in 11 of 14 patients; and renal failure may delay resolution of thrombocytopenia. Due to the method of patient collection, it was not possible to determine an incidence figure. Von Drygalski A, Curtis BR, Bougie DW, McFarland JG, Ahl S, Limbu I, et al. Vancomycin-induced immune thrombocytopenia. *N Engl J Med*. 2007 Mar 1;356(9):904-910.

Diets compared ... Four diets (Atkins, Zone, Ornish, and LEARN) were compared in 311 overweight (BMI 27-40), premenopausal women over 12 months. Weight loss was greatest in women on the Atkins diet, losing a mean of 4.7 kg; this was roughly twice as much as was lost with the other three diets, which did not differ significantly among them. There is a lot of more specific data and rationale’s presented.



Gardner CD, Kiazand A, Alhassan S, Kim S, Stafford RS, Balise RR, et al. Comparison of the Atkins, Zone, Ornish and LEARN diets for change in weight and related risk factors among overweight premenopausal women: The A TO Z weight loss study: A randomized trial. *JAMA*. 2007 Mar 7;297(9):969-977.

Pharmacist salaries ... An annual survey of pharmacist salaries has been released from *Drug Topics*. The good news is: it continues to go up; something to watch: the rate of rise is slowing. There are lots of data broken down in a variety of ways along practice site, degree’s, gender, geography, etc. Overall, the average salary for a retail pharmacist is \$92,291 (\$47/hr) and for an institutional pharmacist, \$97,545 (\$49/hr). However, there is a price ...



Ukens C. Pay dirt: Pharmacist salaries are still climbing, but at a slower rate. Our exclusive survey shows who gets top dollar. *Drug Topics*. 2007 Mar 5.

<http://www.drugtopics.com/drugtopics/article/articleDetail.jsp?id=408159>

Reviews of Note ...

- Zimetbaum P. Amiodarone for atrial fibrillation. *N Engl J Med*. 2007 Mar 1;356(9):935-41.

- Ma RCW, Kong APS, Chan N, Tong PCY, Chan JCN. Drug-induced endocrine and metabolic disorders. *Drug Safety*. 2007;30(3):215-245.
- McKenney JM, Sica D. Prescription omega-3 fatty acids for the treatment of hypertriglyceridemia. *Am J Health-Syst Pharm*. 2007 Mar 15;64:595-605.
- Fontana L, Klein S. Aging, adiposity, and calorie restriction. *JAMA*. 2007 Mar 7;297(9):986-994.

FROM THE LAY LITERATURE about medicine ...

National P&T? ... There are proposals being floated in the Congress concerning a **Comparative Effectiveness Board (CEB)** which would review the value and cost-effectiveness of drugs. This group may even carry out its own clinical trials. As you may imagine, the pharmaceutical industry is not happy about it and the usual dire warnings of no more new drugs were released. Several things are driving the movement including a Democratic majority in Congress, the escalating costs of health care, some of the spectacular costs associated with some newer drugs. Although drug costs account for only about 12% of the U.S. expenditures on health care, it is very visible. It was only a matter of time.

Coghlan A. US aims to break drug industry's hold on pricing. *New Scientist*. 2007 Mar 8; p. 8-9.
<http://www.newscientist.com/channel/health/mg19325943.800>



The last "dose" ...

The Mechanic

A mechanic was removing a cylinder head from the motor of a Harley motorcycle when he spotted a well-known heart surgeon in his shop. The surgeon was there waiting for the service manager to come take a look at his bike when the mechanic shouted across the garage, "Hey Doc, can I ask you a question?"



The surgeon, a bit surprised, walked over to where the mechanic was working on the motorcycle. The mechanic straightened up, wiped his hands on a rag and asked, "So Doc, look at this engine. I open its heart, take the valves out, repair any damage, and then put them back in, and when I finish, it works just like new. So how come I get such a small salary and you get the really big bucks, when you and I are doing basically the same work?"



The surgeon paused, smiled and leaned over, and whispered to the mechanic...

"Try doing it with the engine running"

submitted by Dr. Michael T. Reed

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

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