

AU InforMed

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Key Inforbits

- NEW DRUGS: Aptivus[®]; BiDil[®]
- Summer safety and new narc regulations
- Flush those old drugs?
- Montgomery, AL drug abuse
- Lots of reviews
- Happy Independence Day 

NEW DRUGS, and other related stuff ...

New Drug ... The FDA granted accelerated approval of tipranavir capsules (Aptivus[®] by Boehringer Ingelheim Pharmaceuticals) on June 22, 2005. The approved dose of Aptivus[®] is 500 mg taken with 200 mg of ritonavir (Aptivus[®]), twice daily. Tipranavir must be co-administered with ritonavir to boost the therapeutic levels of tipranavir. Aptivus[®] must be taken in combination with other anti-HIV medications. Tipranavir is a non-peptidic protease inhibitor that works by inhibiting protease, an enzyme needed to complete the HIV replication process. The label carries a 'black box' warning for hepatotoxicity. Aptivus[®] 250 mg soft gel capsules will begin to be available in pharmacies nationwide in about two weeks.

<http://www.boehringer-ingelheim.com/corporate/asp/news/ndetail.asp?ID=2995> (press release)

<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.SearchAction&ApplNo=021814&SearchType=AddlSearch&SEARCHOPTION=B> (drugs@FDA)

New Combo/Indication ... The FDA approved BiDil[®] (hydralazine and isosorbide dinitrate by NitroMed, Inc. of Lexington, MA) on June 23, 2005; it is indicated for the treatment of heart failure in self-identified black patients. It is touted as representing a step toward the promise of personalized medicine. BiDil[®] is a combination of two older drugs, neither of which has been approved alone for heart failure. For this indication, isosorbide seems to work by releasing nitric oxide at the blood vessel wall, and hydralazine may prevent the usual rapid loss of effect. The exact mechanism is not fully known.

FDA. FDA approves BiDil heart failure drug for black patients. *FDA News* 2005 Jun 23; P05-32.

<http://www.fda.gov/bbs/topics/NEWS/2005/NEW01190.html> (Press release)

<http://www.bidil.com/> (NitroMed web site)

<http://www.fda.gov/cder/foi/label/2005/020727lbl.pdf> (Package Label)

FROM THE MEDICAL LITERATURE ...



Summer Safety for Kids ... the American Academy of Pediatrics has a number of patient-friendly brochures available on their website that includes such things as water safety, bugs, sun, all-terrain vehicles, etc. They have just published updated guidelines concerning day camps and resident camps, as well as health guidelines for parents and camp directors. The Academy's web site also provides full text for many resources.

American Academy of Pediatrics. Policy Statement: Health appraisal guidelines for day camps and resident camps. *Pediatrics* 2005 Jun;115(6):1770-73.
<http://www.aap.org/>



New Narc Regs ... The DEA has finalized a rule amendment that allows qualified practitioners, not otherwise registered as a narcotic treatment program, to dispense and prescribe to narcotic dependent persons Schedule III to V drugs for use in maintenance or detoxification treatment. The intent of the rule is to improve the treatment of narcotic-addicted patients and limit diversion. More confusion just in time for those preparing for their state pharmacy boards! Dept of Justice, Drug Enforcement Administration. Authority for practitioners to dispense or prescribe approved narcotic controlled substances for maintenance or detoxification treatment. *Fed Reg* 2005 Jun 26;70(120):36338-44.
<http://a257.g.akamaitech.net/7/257/2422/01jan20051800/edocket.access.gpo.gov/2005/pdf/05-12440.pdf>



Doxycycline for Osteoarthritis ... A recent study in 431 patients has demonstrated the effectiveness of doxycycline for osteoarthritis. Although the patient population was restricted (obese women aged 45-64 years), of the 71% completing the trial, the patients showed a decrease in joint space narrowing and in some measures of pain relief, compared to the placebo group. Brandt KD, Mazzuca SA, Katz BP, et al. Effects of doxycycline on progression of osteoarthritis: Results of a randomized, placebo-controlled, double-blind trial. *Arthritis Rheum* 2005 Jul;52(7):2015-25.
<http://www3.interscience.wiley.com/cgi-bin/jhome/76509746> (limited availability, but worth a try)

Reviews of Note ...

- Zesiewicz TA, Elble R, Louis ED, Hauser RA, Sullivan KL, Dewey RB Jr, et al. Practice Parameter: Therapies for essential tremor: Report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology*. 2005;64:2008-2020.
<http://www.aan.com/professionals/practice/guideline/index.cfm>
- NIH State-of-the-Science Panel. National Institutes of Health State-of-the-Science conference statement: Management of menopause-related symptoms. *Ann Intern Med*. 2005 Jun 21;142(12 pt. 1):1003-13.
- Helfand M, Morton S, Guallar E, Mulrow C, eds. Challenges of summarizing better information for better health: The evidence-based practice center experience. *Ann Intern Med*. 2005 Jun 21;142(Suppl):1033-1125.
[11 articles describing challenges of writing systematic reviews in various areas]
- Swearingen SG, Klausner JD. Sildenafil use, sexual risk behavior, and risk for sexually transmitted diseases, including HIV infection. *Am J Med*. 2005 Jun;118(6):571-77.
- Greene EL, Thomas CR, eds. Minority health and disparities-related issues: Part I. *Med Clin N Am*. 2005 Jul;89(4):721-919. (10 articles)
- Douglas RM, Hemilä H. Vitamin C for preventing and treating the common cold. *PLoS Medicine* 2005 Jun;2(6):e168-9.
<http://medicine.plosjournals.org/perlserv/?request=index-html&issn=1549-1676>
[Short article that updates a large Cochrane Review (2004, 47 pgs), that is also available by accessing this web site.]
- Solomon DH. Selective cyclooxygenase 2 inhibitors and cardiovascular events. *Arthritis Rheum* 2005 Jul;52(7):1968-78.
<http://www3.interscience.wiley.com/cgi-bin/jhome/76509746> (limited availability)
- Snead OC III, Gibson KM. γ -Hydroxybutyric acid. *N Engl J Med* 2005 Jun 30;352(26):2721-32.

FROM THE LAY LITERATURE about medicine ...



Dose may be higher than you think ... The U.S. Geological Survey has published a report, and is the subject of a story in the *Washington Post*, about pharmaceuticals in our water supply. The report was a long time coming, not complete and raises many questions. Bottom line: don't flush those medicines down the toilet! From 139 waterway samples across the U.S., the percent of waterways containing traces of drugs included: Steroids in 89%, OTC drugs in 81% and antibiotics in 48%. Various other chemicals and drugs were also found.

Eilperin J. Pharmaceuticals in waterways raise concern. *Washington Post.com* 2005 Jun 23; p. A03.

<http://www.washingtonpost.com/wp-dyn/content/article/2005/06/22/AR2005062201988.html?referrer=email>



Americans get fatter as their wallets get thinner ... A new study has reported that private health insurance spending related to obesity has increased dramatically over the last 15 years, over 10 times! This is demonstrated in the amounts spent for cardiovascular disease, diabetes, hyperlipoproteinemia and other weight-related problems. Approximately 31% of US adults are obese. This is up from 23% in the 1980's and 15% in the 1970's.

Hellmich N. Health spending soars for obesity. *USA Today.com* 2005 Jun 26.

http://www.usatoday.com/news/health/2005-06-26-health-spending-obesity_x.htm (USA Today)

Thorpe KE, Florence CS, Howard DH, Joski P. The rising prevalence of treated disease: Effects on private health insurance spending. *Health Affairs* 2005 Jun 27; W5-317-325 (web exclusive)

<http://content.healthaffairs.org/webexclusives/index.dtl?year=2005> (Health Affairs article, limited free distribution)

Career Option ... Corporate Pharmacist ... How would it feel to make a recommendation for a patient to take their atorvastatin once daily instead of twice, and save the company \$1 million per year? That is part of the work day for THE corporate pharmacist for General Motors. As part of a team, the pharmacist is working to, in essence, save the company by helping to reduce costs; in this case health care costs. Great story.

Green J. GM pharmacist prescribes tougher look at how workers take pills. *Bloomberg.com* 2005 Jun 23.

<http://www.bloomberg.com/apps/news?pid=10000103&sid=aUJYbf.D1ubM&refer=us>



UVA, UVB, UV something ... Interesting article in the *Washington Post* about sunscreens and the "current thinking" on blocking UVA and UVB wavelengths. UVA was previously thought to be less important than UVB when considering sun-induced skin damage; not anymore. This isn't peer-reviewed literature, but you may have patients asking the questions.

Huget J. Less than full protection. *Washington Post.com* 2005 Jun 28; p. HE01.

<http://www.washingtonpost.com/wp-dyn/content/article/2005/06/27/AR2005062701099.html?referrer=email>

Rx Abuse, Montgomery flavor ... Although not a big news story, this one gives a more local flavor of prescription drug abuse in Alabama. No surprise that the items of interest are primarily narcotic pain relievers and the methods of obtaining them are tried and true. One message is that the methods of obtaining new or refill prescriptions may change. Submitted by R. Lee Evans, Pharm.D.

Roney M. Prescription drug abuse bitter pill for tri-county. *Montgomery Advertiser* 2005 Jun 27.

<http://www.montgomeryadvertiser.com/NEWSV5/storyV5DOPE27W.htm>

Bad news coming about Medicaid reimbursement? ... According to a recent article, two government reports prepared by the Inspector General for the Dept. of Health and Human Services which are to be used in testimony at a Senate Finance Committee hearing June 29, 2005, Medicaid overpays for prescription drugs. Perhaps more importantly, the target is the pharmacist based on reimbursement for AWP or WAC. It also revolves around the reimbursement rates for generic vs. brand. For whatever good it does, one spokesman for the NACDS reminds us that if you look at total reimbursement vs. percent “profit” the pharmacist is not the one getting rich.

Lueck S. Medicaid overpays for medications, U.S. reports say. *Wall Street Journal.com* 2005 Jun 29; p. D5.

NEW RESOURCES in the DILRC ...

- Habif TP, Campbell JL Jr., Capman MS, Dinulos JGH, Zug KA. *Skin Disease: Diagnosis and Treatment*. 2nd ed. St. Louis: Elsevier Mosby, 2005.
- Cuéllar LM, Ginsburg DB. *Preceptor’s Handbook for Pharmacists*. Bethesda, MD: American Society of Health-System Pharmacists, 2005.

The last “dose” ...

“Perseverance and spirit have done wonders in all ages.”

-General George Washington [1732-1799]



Happy Independence Day

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

Auburn University, Harrison School of Pharmacy, Drug Information Center

• Phone 334-844-4400 • Fax 334-844-8366 • <http://www.pharmacy.auburn.edu/dilrc/dilrc.htm>

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