

# AU InforMed

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## Key Inforbits

- Intal nebulizer solution discontinued
- Beware – mandatory switch to HFA coming
- Home blood pressure monitoring recommended
- Vaccine recommendations for elderly, pregnant
- New use for Preparation H
- D-Day anniversary

## **NEW DRUGS, and other related stuff ...**

**MedWatch** ... (5/15/2008) Following publication of the Blood conservation using antifibrinolytics: A randomized trial in a cardiac surgery population (BART) study in the May 14, 2008 online issue of the *New England Journal of Medicine*, Bayer Pharmaceuticals notified the FDA of their intent to remove **all remaining supplies of Trasyolol (aprotinin injection)** from hospital pharmacies and warehouses. Under a limited use agreement, access to Trasyolol is limited to investigational use of the drug according to the procedures described in a special treatment protocol. Read the complete MedWatch safety summary, including links to the updated drug information page and the FDA news statement, at:

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

**MedWatch** ... (5/16/2008) FDA is aware of reports of infants born with **serious congenital anomalies, including microtia and cleft lip and palate, following exposure to mycophenolate mofetil (MMF) during pregnancy**. MMF, the active drug substance in CellCept, is an ester of the active metabolite mycophenolic acid (MPA), the active drug substance in Myfortic. In most cases, the mothers were taking MMF following an organ transplant to prevent organ rejection. However, some mothers taking MMF were being treated for immune-mediated conditions such as systemic lupus erythematosus (SLE) and erythema multiforme. MMF and MPA increase the risk of spontaneous abortion in the first trimester and can cause congenital malformations in the offspring of women who are treated during pregnancy. See the FDA Healthcare Professional Information Sheet containing considerations and recommendations for clinicians prior to prescribing MMF or MPA to women of childbearing potential.

Read the entire 2008 MedWatch Safety Summary, including a link to the FDA Alert and Healthcare Professional Information Sheet regarding this issue at:

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

**MedWatch** ... (5/19/2008) Medicis and FDA notified healthcare professionals of **the recall** of lot numbers B080037 (Exp: 12/09) and B080038 (Exp: 12/09) of **Solodyn<sup>®</sup>** (minocycline) Extended Release Tablets. The product was recalled because one of the bottles contained Azasan<sup>®</sup> (azathioprine tablets) 75mg instead of Solodyn<sup>®</sup> 90mg Tablets. Taking Azasan<sup>®</sup> instead of Solodyn<sup>®</sup> presents a health hazard and safety risk to patients. Healthcare professionals are urged to check their inventory and pull the referenced lot numbers from their stock and make arrangements with the manufacturer to return the product.

Read the entire 2008 MedWatch Safety Summary, including a link to the manufacturer's press release regarding this issue at:

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

**MedWatch** ... (5/27/2008 and 5/30/2008) The FDA announced **not to buy or use Xiadafil VIP Tablets** sold in bottles of 8 tablets (Lot #6K029) or blister cards of 2 tablets (Lot# 6K029-SEI). The product is marketed as a dietary supplement and is promoted and sold over the internet for sexual enhancement and to treat erectile dysfunction (ED). In addition, International Pharmaceuticals, Ltd. and FDA announced that the company is recalling all supplement products sold under the brand name of Viril-ity Power (VIP) Tablets. Both products contains a potentially harmful, undeclared ingredient that may dangerously affect a person's blood pressure and can cause other life-threatening side effects, hydroxyhomosildenafil, an analog of sildenafil, the active ingredient in Viagra. The undeclared ingredient may interact with nitrates found in some prescription drugs and can lower blood pressure to life-threatening levels. Read the 2008 MedWatch Safety Summary, including a link to the Agency's News Release at:

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

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

**Discontinued** ... (5/30/2008) **Intal Nebulizer Solution (cromolyn sodium inhalation solution)** has been discontinued by the manufacturer, King Pharmaceuticals. Current supplies will be allowed to be exhausted. It is apparently a marketing-based decision.

[http://www.fda.gov/cder/drug/shortages/IntalDHCP\\_2008.pdf](http://www.fda.gov/cder/drug/shortages/IntalDHCP_2008.pdf)

**MedWatch** ... (6/4/2008) FDA issued an Early Communication About an Ongoing Safety Review to inform healthcare professionals that the Agency is investigating a possible association between the use of **Tumor Necrosis Factor (TNF) blockers and the development of lymphoma and other cancers in children and young adults**. FDA is investigating approximately 30 reports of cancer in children and young adults over a ten-year interval, beginning in 1998. Long-term studies are necessary to provide definitive answers about whether TNF blockers increase the occurrence of cancers in children because cancers may take a long time to develop and may not be detected in short-term studies.

Read the entire 2008 MedWatch Safety Summary, including a link to the FDA's Early Communication About an Ongoing Safety Review of Tumor Necrosis Factor (TNF) Blockers regarding this issue at: <http://www.fda.gov/medwatch/safety/2008/safety08.htm#TNF>

**CFC switch to HFA coming** ... (5/30/2008) The FDA issued a public health advisory alert to switch to hydrofluoroalkane (HFA)-propelled albuterol inhalers because chlorofluorocarbon (CFC)-propelled inhalers will not be available in the United States after Dec. 31, 2008. CFC-propelled albuterol inhalers are being phased out because they are harmful to the environment by contributing to depletion of the ozone layer. Three HFA-propelled albuterol inhalers have been approved by the FDA: Proair HFA Inhalation Aerosol, Proventil HFA Inhalation Aerosol, and Ventolin HFA Inhalation Aerosol. In addition, an HFA-propelled inhaler containing levalbuterol, is available as Xopenex HFA Inhalation Aerosol. HFA-propelled albuterol inhalers may taste and feel different than the CFC-propelled albuterol inhalers. Patients must also prime and clean HFA-propelled albuterol inhalers. Each HFA-propelled albuterol inhaler has different priming, cleaning, and drying instructions, and patients should read and understand the instructions first before using the inhaler. For more information:

<http://www.fda.gov/cder/mdi/albuterol.htm>

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01842.html>

## **FROM THE MEDICAL LITERATURE ...**

**Home BP monitoring recommended ...** The American Heart Association, the American Society of Hypertension and the Preventive Cardiovascular Nurses Association have issued a joint statement with several recommendations encouraging patient home blood pressure monitoring. A primary rationale is that home monitoring is more accurate, giving a truer picture of actual daily blood pressures, particularly when done more than once per day and eliminates the “white coat hypertension” component of office visits. Oscillometric monitors used on the upper arm are recommended, among several other more specific recommendations.



Pickering TG, Chair, Miller NH, Ogedegbe G, Krakoff LR, Artinian NT, Goff D. Call to action on use and reimbursement for home blood pressure monitoring: Executive summary: A joint statement from the American Heart Association, the American Society of Hypertension and the Preventive Cardiovascular Nurses Association. Hypertension. 2008;52: DOI: 10.1161/HYPERTENSIONAHA.107.189011.

**Zoster vaccine is recommended for all persons aged >60 years ...** These recommendations represent the first statement by the Advisory Committee on Immunization Practices (ACIP) on the use of a live attenuated vaccine for the prevention of herpes zoster (zoster) (i.e., shingles) and its sequelae. It was licensed by the FDA on May 25, 2006. This report summarizes the epidemiology of zoster and its sequelae, describes the zoster vaccine, and provides recommendations for its use among adults aged >60 years in the United States.

Harpaz R, Ortega-Sanchez IR, Seward JF. Prevention of Herpes Zoster: Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR. 2008 May 15;57:1-30.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr57e0515a1.htm>

**ACIP recommendations for Tdap vaccine for pregnant and postpartum women ...** A new report from the Advisory Committee on Immunization Practices (ACIP) describes the clinical features of pertussis, tetanus, and diphtheria among pregnant and postpartum women and their infants; reviews evidence of pertussis vaccine during pregnancy as a strategy to prevent infant pertussis; summarizes Tdap (tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis) vaccination policy in the US and; presents recommendations for use of Td (tetanus and diphtheria toxoids) and Tdap vaccines among pregnant and postpartum women.

Murphy TV, Slade BA, Broder KR, Kretsinger K, Tiwari T, Joyce MP, et al. Prevention of pertussis, tetanus, and diphtheria among pregnant and postpartum women and their infants; Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR. 2008 May 14;57:1-53.

<http://www.cdc.gov/mmwr/pdf/rr/rr57e0514.pdf>

### **Reviews of Note ...**

- Horvath K, Jeitner K, Siering U, Soz D, Stich AK, Soz-Päd D, et al. Long-term effects of weight-reducing intervention in hypertensive patients. Arch Intern Med. 2008 Mar 24;168(6):571-580.
- Abramowicz M, ed. Diet, drugs and surgery for weight loss. Med Lett Treat Guide. 2008 Apr;6(68):23-30.
- Ebeling PR. Osteoporosis in men. N Engl J Med. 2008 Apr 3;358(14):1474-1482.
- Zimmermann C, Riechelmann R, Krzyzanowska M, Rodin G, Tannock I. Effectiveness of specialized palliative care: A systematic review. JAMA. 2008 Apr 9;299(14):1698-1709.
- Abramowicz M, ed. Which statin? Med Lett Drugs Ther. 2008 Apr 21;50(1284):29-31.

## FROM THE LAY LITERATURE about medicine ...

**Off-label use of Preparation H® – Lady magnet ...** According to news reports, a new use of Preparation H® has surfaced. In some of the ‘clubbing’ scenes, the product is being used by young men to give their torso a “ripped” look (good muscle definition). The theory of using Preparation H® appears to be that the vasoconstrictor component (phenylephrine) will shrink the outer layer of tissue, to temporarily show off musculature. We are looking for testimonials if anyone wants to share.



*-submitted by Wesley T. Lindsey, Pharm.D.*

Cox L. Preparation H finds place in club circuit. ABC News Medical Unit.

<http://abcnews.go.com/Health/SkinCare/story?id=4966867&page=1>

**The West is winning in hazardous lifestyles ...** While the popularity of various cultures and lifestyles ebbs and flows, it appears the Western world is ‘winning’ in terms of some bad habits (eg, smoking). A dubious distinction in that, according to the World Health Organization, the major killers worldwide will become noncommunicable diseases such as heart disease, cancer, diabetes and traffic accidents. This is instead of infectious diseases such as AIDS, tuberculosis and malaria. This is partly brought about by the generally increasing affluence across the world. In areas such as Africa, infectious disease will be prominent for a long time, but areas such as Asia may see significant increases in these self-induced maladies.

McNeil DG Jr. Noninfectious illnesses are expected to become top killers. New York Times. 2008 Jun 3.

<http://www.nytimes.com/2008/06/03/health/research/03glob.html>

## AUBURN HSOP FACULTY and STUDENTS in the literature ...

- Hornsby LB, Hester EK, Donaldson AR. Potential interaction between warfarin and high dietary protein intake. *Pharmacotherapy*. 2008 Apr;28(4):536-539.
- Wargo K, Roark K, Ibrahim F. Autoimmune-hemolytic anemia associated with montelukast and zafirlukast therapy in a patient with hepatitis C. *Hosp Pharm*. 2008 Apr;43:300-302, 306.



### The last “dose” ...

The tide has turned.

The free men of the world are marching together to victory. I have full confidence in your courage, devotion to duty, and skill in battle.

We will accept nothing less than full victory.

Good luck, and let us all beseech the blessings of Almighty God upon this great and noble undertaking.

Dwight D. Eisenhower [1890 - 1969] on June 6, 1944, prior to the D-Day invasion



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