

AU InforMed

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Key Inforbits

- Orphan, Rx-to-OTC, new/old drug
- Facts and figures about Diabetes
- Several new vaccination schedules
- Dabigatran included in A-Fib Guidelines
- “Effectiveness-based” guidelines
- President’s Day festivities

NEW DRUGS, and other related stuff ...

New Orphan Drug ... (2/9/2011) Neuralstem, Inc. announced that the FDA's Office of Orphan Products Development has granted it orphan drug designation for the treatment of Amyotrophic Lateral Sclerosis (ALS, also known as Lou Gehrig's disease) with its human spinal cord derived neural stem cells (NSI-566RSC), currently in a Phase I safety study to evaluate the safety of the product and the surgical route of administration in a wide range of ALS patients. <http://investor.neuralstem.com/phoenix.zhtml?c=203908&p=irol-newsArticle&ID=1527036&highlight=>

Rx → OTC ... (1/25/2011) The FDA has approved the move from prescription only to over-the-counter status for the Allegra[®] (fexofenadine) family of products. The availability of these products is expected in March 2011.

U.S. FDA approves number one U.S.-prescribed allergy treatment Allegra for over-the-counter use. Press Release. Bridgewater, NJ/Chattanooga, TN; Sanofi-Aventis/Chattem. 2011 Jan 25. <http://www.allegra.com/>

New(?) Drug ... (2/4/2011) The FDA has approved **Makena[™] (hydroxyprogesterone caproate)** by Hologic, Inc., based in Sunnyvale, California) injection to reduce the risk of preterm delivery before 37 weeks of pregnancy, in pregnant women with a history of at least one spontaneous preterm birth. The drug is not intended for use in women with a multiple pregnancy, such as a twin pregnancy, or other risk factors for preterm birth. The FDA approved Makena[™] under the agency's accelerated approval regulations that allow promising drugs to be approved based on a surrogate endpoint benefit (here, reducing the risk of delivery before 37 weeks of pregnancy) that is reasonably likely to predict a clinical benefit. Dosing is once a week by injection into the hip. Treatment should begin at 16 weeks and no later than 21 weeks of pregnancy. The most common side effects reported included pain, swelling, or itching at the injection site; hives, nausea and diarrhea. Serious adverse reactions were rare; one report each of pulmonary embolism and an injection site infection.

The FDA originally approved hydroxyprogesterone caproate under the trade name Delalutin[®] in 1956 for use in pregnant women. The approved indications include threatened miscarriage. The original manufacturer requested the withdrawal of Delalutin[®] from the market in 2000 for reasons unrelated to safety.

FDA approves drug to reduce risk of preterm birth in at-risk pregnant women. FDA News. 2011 Feb 4. <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm242234.htm>

FROM THE MEDICAL LITERATURE ...

New Diabetes Facts and Figures ... from the CDC ... Nearly 26 million (8.3%) Americans have diabetes, according to new estimates from the Centers for Disease Control and Prevention (CDC) and about 27% of those (7 million) do not know it. In addition, 79 million U.S. adults are estimated to have prediabetes which raises a person's risk of type 2 diabetes, heart disease and stroke. Prediabetes affects 35% of adults aged 20 and older. The 2011 estimates have increased from 2008 for several reasons: More people are developing diabetes; Many people are living longer with diabetes; Hemoglobin A1c is newly incorporated as a diagnostic test. For all the data, see the two references below.

More than a third of adults estimated to have prediabetes. Press Release. Atlanta: Centers for Disease Control and Prevention. 2011 Jan 13. Available at: http://www.cdc.gov/media/releases/2011/p0126_diabetes.html
National Diabetes Fact Sheet, 2011. Atlanta: Centers for Disease Control and Prevention. Available at: http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2011.pdf

General Recommendations on Immunization Updated ... Last updated in 2006 this statement by the Advisory Committee on Immunization Practices (ACIP) updates a variety of more specific reports issued by the ACIP. Revisions include 1) changes to the tables of contraindications and precautions to vaccination, conditions commonly misperceived as contraindications and precautions; 2) reorganization of the report content; 3) updated storage criteria and 4) updated revisions for vaccination of patients who have received a hematopoietic cell transplant.

General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR. 2011 Jan 28;60(RR02):1-60.

http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm?s_cid=rr6002a1_x

Meningococcal Conjugate Vaccine Recommendations Updated ... for the use of quadrivalent (serogroups A, C, Y, and W-135) meningococcal conjugate vaccines (Menveo[®], Novartis; and Menactra[®], Sanofi Pasteur) in adolescents and persons at high risk for meningococcal disease. This report summarizes two new recommendations by Advisory Committee on Immunization Practices (ACIP): 1) routine vaccination of adolescents, preferably at age 11 or 12 years, with a booster dose at age 16 years and 2) a 2-dose primary series administered 2 months apart for persons aged 2 through 54 years with persistent complement component deficiency and functional or anatomic asplenia, and for adolescents with HIV infection.

Updated Recommendations for Use of Meningococcal Conjugate Vaccines – Advisory Committee on Immunization Practices (ACIP), 2010. MMWR. 2011 Jan 28(60(3):72-76.

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6003a3.htm?s_cid=mm6003a3_x

Recommended Adult Immunization Schedule for 2011 ... In October 2010, the Advisory Committee on Immunization Practices (ACIP) approved the adult immunization schedule for 2011, which includes several changes. Some of the changes include: expanded recommendation for annual influenza vaccination for all persons aged 6 months and older; a permissive recommendation for use of tetanus, diphtheria, and acellular pertussis (Tdap) vaccine in adults aged 65 years and older, regardless of the time elapsed since the most recent tetanus and diphtheria toxoids (Td)--containing vaccine; and a recommendation for a 2-dose series of meningococcal vaccine in adults with certain high-risk medical conditions. The usual colored summary table is included.

Recommended Adult Immunization Schedule – United States, 2011. MMWR. 2011 Feb 4;60(04):1-4.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6004a10.htm>

Child vaccination recommendations – CDC ... Each year, the Advisory Committee on Immunization Practices (ACIP) publishes immunization schedules for persons aged 0 through 18 years. Changes to the previous schedules include:

Guidance for hepatitis B vaccine schedule for children who did not receive a birth dose.

Added information on use of 13-valent pneumococcal conjugate vaccine.

Guidance for administration of 1 or 2 doses of seasonal influenza vaccine based upon the child's history of monovalent 2009 H1N1 vaccination.

Use of tetanus and diphtheria toxoids, and acellular pertussis (Tdap) vaccine among children aged 7 through 10 years who are incompletely vaccinated against pertussis.

Added routine 2-dose schedule of quadrivalent meningococcal conjugate vaccine (MCV4) for certain persons at high risk for meningococcal disease, and recommendations for a booster dose of MCV4.

Guidance for use of Haemophilus influenzae type b (Hib) vaccine in persons aged 5 years and older in the catch-up schedule has been condensed.

Recommended Immunization Schedules for Persons Aged 0 Through 18 Years-United States, 2011. MMWR. 2011 Feb 11;60(05):1-4.

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6005a6.htm?s_cid=mm6005a6_w

A-Fib guidelines updated for dabigatran ... The American College of Cardiology, the American Heart Association and the Heart Rhythm Society have updated their guidelines on treating atrial fibrillation to include the new oral anticoagulant dabigatran (Pradaxa®). Using dabigatran vs. warfarin should be based upon whether the patient can adhere to twice-daily dosing, patient preference, cost, and available INR monitoring.

Wann LS, Curtis AB, Ellenbogen KA, Estes NAM 3rd, Ezekowitz MD, Jackman WM, January CT, Lowe JE, Page RL, Slotwiner DJ, Stevenson WG, Tracy CM, writing on behalf of the 2006 ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation Writing Committee. 2011 ACCF/AHA/HRS focused update on the management of patients with atrial fibrillation (update on dabigatran): a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *Circulation*. 2011;123:●●●.

<http://circ.ahajournals.org/cgi/reprint/CIR.0b013e31820f14c0v1>

“Effectiveness-based” Guidelines, CV disease prevention in women ... In addition to the title change from "Evidence-Based" to "Effectiveness-Based" other changes include:

"High risk" in women is defined as being at a 10% or greater 10-year risk for all cardiovascular disease, not just coronary heart disease;

Racial, ethnic, and socioeconomic factors should be considered as to how they affect cardiovascular risk;

Women with existing cardiovascular disease should be screened for depression;

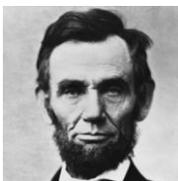
Women with systemic lupus erythematosus and rheumatoid arthritis should be considered at risk for cardiovascular disease and be screened for other risk factors;

Pregnancy complications (eg, preeclampsia, gestational diabetes, preterm birth), should be taken into account when cardiovascular risks are evaluated later in their lives.

Mosca L, Benjamin EJ, Berra K, Bezanson JL, Dolor RJ, Lloyd-Jones DM, Newby LK, Pinˆa IL, Roger VL, Shaw LJ, Zhao D; Beckie TM, Bushnell C, D'Armiento J, Kris-Etherton PM, Fang J, Ganiats TG, Gomes AS, Gracia CR, Haan CK, Jackson EA, Judelson DR, Kelepouris E, Lavie CJ, Moore A, Nussmeier NA, Ofili E, Oparil S, Ouyang P, Pinn VW, Sherif K, Smith SC Jr, Sopko G, Chandra-Strobos N, Urbina EM, Vaccarino V, Wenger NK.

Effectiveness-based guidelines for the prevention of cardiovascular disease in women—2011 update: a guideline from the American Heart Association. *Circulation*. 2011;123:●●●-●●●.

<http://circ.ahajournals.org/cgi/reprint/CIR.0b013e31820faaf8v1>



Reviews of Note ...

- Fiore AE, Fry A, Shay D, Gubareva I, Bresee JS, Uyeki TM. Antiviral agents for the treatment and chemoprophylaxis of influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR*. 2011 Jan 21;60(Supp 1):1-26.
- Ranpura V, Hapani S, Wu S. Treatment-related mortality with bevacizumab in cancer patients: A meta-analysis. *JAMA*. 2011 Feb 2;305(5):487-494.
- Neogi T, Gout. *N Engl J Med*. 2011 Feb 3;364(5):443-452.
- Hall E, Frey BN, Soares CN. Non-hormonal treatment strategies for vasomotor symptoms: A critical review. *Drugs*. 2011;71(3):287-304.
- Skevaki CL, Galani JE, Pararas MV, Giannopoulou KP, Tsakris A. Treatment of viral conjunctivitis with antiviral drugs. *Drugs*. 2011;71(3):331-347.
- Crostall JD, Mckeage K. Fulvestrant: A review of its use in the management of hormone receptor-positive metastatic breast cancer in postmenopausal women. *Drugs*. 2011;71(3):363-380.
- Gray CL, Walters-Smith NE. Febuxostat for treatment of chronic gout. *Am J Health-Syst Pharm*. 2011 Mar 1;68:389-398.

NEW RESOURCES in the DIC ...

- Who's Who in Managed Care Pharmacy, 2010-2011. Alexandria, VA: Academy of Managed Care Pharmacy, 2010.



The last "dose" ...

Gettysburg Address [November 19, 1863]

"Fourscore and seven years ago our fathers brought forth on this continent a new nation, conceived in liberty and dedicated to the proposition that all men are created equal. Now we are engaged in a great civil war, testing whether that nation or any nation so conceived and so dedicated can long endure. We are met on a great battlefield of that war. We have come to dedicate a portion of that field as a final resting-place for those who here gave their lives that that nation might live. It is altogether fitting and proper that we should do this. But in a larger sense, we cannot dedicate, we cannot consecrate, we cannot hallow this ground. The brave men, living and dead who struggled here have consecrated it far above our poor power to add or detract. The world will little note nor long remember what we say here, but it can never forget what they did here. It is for us the living rather to be dedicated here to the unfinished work which they who fought here have thus far so nobly advanced. It is rather for us to be here dedicated to the great task remaining before us--that from these honored dead we take increased devotion to that cause for which they gave the last full measure of devotion--that we here highly resolve that these dead shall not have died in vain, that this nation under God shall have a new birth of freedom, and that government of the people, by the people, for the people shall not perish from the earth."

Abraham Lincoln [February 12, 1809 – April 15, 1865]

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