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Key Inforbits

- New drug - belatacept (Nulojix[®])
- Sunscreen standards revised by the FDA
- High dose warning for simvastatin
- Food pyramid revised to My Plate
- NSTEMI and Vitamin D guidelines revised
- Food-specific diet recommendations

NEW DRUGS, and other related stuff ...

New Drug ... (6/15/2011) The FDA has approved **belatacept (Nulojix[®])** by Bristol-Myers Squibb Company, Princeton, N.J.) to prevent acute rejection in adult patients who have had a kidney transplant. The drug is approved for use with other immunosuppressants (medications that suppress the immune system), specifically basiliximab, mycophenolate mofetil, and corticosteroids. Belatacept is a selective T-cell costimulation blocker. By preventing rejection, the drug, given through 30 minute intravenous infusions, works with other immunosuppressants to keep the new kidney working. Nulojix[®] carries a Boxed Warning for an increased risk of developing **post-transplant lymphoproliferative disorder (PTLD)**, a type of cancer where white blood cells grow out of control after an organ transplant. The risk of PTLD is higher for transplant patients who have never been exposed to Epstein-Barr virus (EBV), the cause of mononucleosis. Transplant patients who have not been exposed to EBV have more difficulty mounting an effective immune response to the virus if they get infected after transplant; typically they get exposed to the virus at time of transplant, as it is carried in around 80 percent of donated organs. Patients should be tested for EBV and should only receive Nulojix[®] if the test shows they have already been exposed to EBV. Another Boxed Warning warns of an **increased risk of serious infections and other cancers**. Common adverse reactions include anemia, constipation, kidney or bladder infection, and swollen legs, ankles, or feet. Any transplant patients, including those receiving belatacept, should limit the amount of time spent in sunlight because of the risk of skin cancer and should not get live vaccines because of the risk of infection.

FDA approves Nulojix for kidney transplant patients. FDA News Release. 2011 Jun 15.

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm259184.htm>

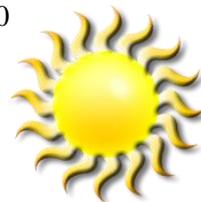
http://packageinserts.bms.com/pi/pi_nulojix.pdf [Package Insert]

New Information ... on **sunscreens** (6/14/2011) The FDA has announced that sunscreen products meeting modern standards for effectiveness may be labeled with new information to help consumers reduce the risk of skin cancer and early skin aging, as well as help prevent sunburn. The final regulation allows sunscreen products that pass the FDA's test for protection against both ultraviolet A (UVA) and ultraviolet B (UVB) rays to be labeled as "Broad Spectrum." Both UVB and UVA radiation contribute to sunburn, skin cancer, and premature skin aging. Sunburn is primarily caused by UVB radiation.

Under the new labeling, sunscreens labeled as both Broad Spectrum and SPF 15 (or higher), if used regularly, as directed, and in combination with other sun protection measures will help prevent sunburn, reduce the risk of skin cancer, and reduce the risk of early skin aging.

In addition to the final rule for sunscreen labeling,

- A proposed rule would limit the maximum SPF value on sunscreen labels to “50 +”, because there is not sufficient data to show that products with SPF values higher than 50 provide greater protection for users than products with SPF values of 50.
- An Advance Notice of Proposed Rulemaking (ANPR) will allow the public a period of time to submit requested data addressing the effectiveness and the safety of sunscreen sprays and to comment on possible directions and warnings for sprays that the FDA may pursue in the future, among other issues regarding dosage forms for sunscreens.



The new regulations will become effective for most manufacturers in one year. Manufacturers with annual sales less than \$25,000 have two years to comply.

FDA Announces Changes to Better Inform Consumers About Sunscreen. FDA Press Release. 2011 Jun 14.

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm258940.htm>

New Formulation ... (6/20/2011) Pfizer Inc. and Acura Pharmaceuticals Inc. announced that the FDA has approved **Oxecta™ (oxycodone HCl, USP) Tablets CII**. Oxecta™ is indicated for the management of acute and chronic moderate to severe pain where the use of an opioid analgesic is appropriate. Oxecta™ is the first immediate-release oxycodone HCl using technology designed to discourage common methods of tampering associated with opioid abuse and misuse. This AVERSION® Technology is a unique composition of common pharmaceutical ingredients that, for example, cause the active ingredient to gel to prevent injection or to irritate nasal passages to discourage inhalation. Pfizer is licensing the technology from Acura.

Pfizer/Acura Announce FDA Approval of Oxecta™ (Oxycodone HCL, USP) CII. Pfizer Press Release. 2011 Jun 20

http://www.pfizer.com/news/press_releases/pfizer_press_releases.jsp#guid=20110620005857en&source=RSS_2011&page=1

Jeffrey S. FDA approves tamper-resistant oxycodone. MedScape Medical News. 2011 Jun 20.

http://www.medscape.com/viewarticle/744935?ssdmh=dm1.696925&src=nl_newsalert

MedWatch ... (6/8/2011) The FDA notified healthcare professionals that it is recommending limiting the use of the highest approved dose of the cholesterol-lowering medication **simvastatin 80 mg** (Zocor® or in combinations such as Vytorin® and Simcor®) because of increased risk of muscle damage. Patients taking simvastatin 80 mg daily have an increased risk of myopathy compared to lower doses of this drug or other drugs in the same class. This risk appears to be higher during the first year of treatment, is often the result of interactions with certain medicines, and is frequently associated with a genetic predisposition toward simvastatin-related myopathy. The most serious form of myopathy, rhabdomyolysis, can damage the kidneys and lead to kidney failure which can be fatal. FDA is requiring changes to the simvastatin label to add new contraindications (should not be used with certain medications) and dose limitations for using simvastatin with certain medicines.



RECOMMENDATION: Simvastatin 80 mg should not be started in new patients, including patients already taking lower doses of the drug.

Read the MedWatch safety alert, including links to the FDA Drug Safety Communication, Press Release, and Consumer Update, at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm258384.htm>

FROM THE MEDICAL LITERATURE ...



MyPlate ... Amid all of the hoopla of a government rollout, at long last, the replacement for the food pyramid. It is designed to be a simpler and easier to understand reminder of what constitutes a healthy meal/diet. The *2010 Dietary Guidelines for Americans*, launched in January of this year, form the basis of the federal government's nutrition education programs, federal nutrition assistance programs, and dietary advice provided by health and nutrition professionals. For further information on this program, see the websites below.

First Lady, Agriculture Secretary Launch *MyPlate* Icon as a New Reminder to Help Consumers to Make Healthier Food Choices. U.S. Dept. of Agriculture, Press Release. 2011 Jun 2.

<http://www.cnpp.usda.gov/Publications/MyPlate/PressRelease.pdf>

Choose My Plate website. U.S. Dept of Agriculture. 2011 May 31. <http://www.choosemyplate.gov/>

Report of the Dietary Guidelines Advisory Council on the Dietary Guidelines for Americans, 2010.

<http://www.cnpp.usda.gov/Publications/DietaryGuidelines/2010/DGAC/Report/A-ExecSummary.pdf>

http://www.choosemyplate.gov/images/MyPlateImages/JPG/myplate_green.jpg

“Focused update of guidelines” ... from the American College of Cardiology and the American Heart Association, an update on the management of patients with unstable angina/non–ST-elevation myocardial infarction (NSTEMI). Just the update is over 40 pages, so happy reading. Wright RS, Anderson JL, Adams CD, Bridges CR, Casey DE Jr, Ettinger SM, Fesmire FM, Ganiats TG, Jneid H, Lincoff AM, Peterson ED, Philippides GJ, Theroux P, Wenger NK, Zidar JP. 2011 ACCF/AHA focused update of the guidelines for the management of patients with unstable angina/non–ST-elevation myocardial infarction (updating the 2007 guideline): a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *Circulation*. 2011;123:2022–2060.

<http://circ.ahajournals.org/cgi/reprint/123/18/2022>

Clinical Practice Guideline ... Guidance for Vitamin D deficiency ... The Endocrine Society, using an evidence-based, consensus approach developed a clinical practice guideline for vitamin D deficiency. The Society recommends vitamin D supplementation within parameters of age and circumstance. They also recommend measuring 25-hydroxyvitamin D levels by a reliable assay as an initial determination of deficiency. Due to lack of evidence it is not recommended to screen patients not at risk of vitamin D deficiency or to prescribe it for noncalcemic issues (eg, cardiovascular benefit).



Holick MF, Binkley NC, Bischoff-Ferrari HA, Gordon CM, Hanley DA, Heaney RP, Murad NH, Weaver CM. Evaluation, treatment, and prevention of vitamin D deficiency: An endocrine society clinical practice guideline. *J Clin Endocrinol Metab*. 2011 Jun 6 (online);96(7): doi:10.1210/jc.2011-0385.

Advice on diet and lifestyle gets specific ... A recent prospective study of 120,877 men and



women with long term follow up (four year intervals) yielded a detailed history of weight changes and was able to tie specific foods and behaviors to weight gain/loss. Amongst the foods most strongly correlated with weight gain were potato chips, potatoes, and sugar-sweet drinks while those associated with weight loss included fruits, vegetables, yogurt, and grains. Each of these was

associated with a specific weight gain/loss, eg, potato chips accounted for an increase of 1.69 lbs while eating fruits was associated with a 0.49 lb weight loss. Lifestyle changes such as physical activity, alcohol use and smoking were quantitated with expected loss/gains. Even the amount of sleep and television viewing was measured in terms of weight.

Mozaffarian D, Hao T, Rimm EB, Willett WC, Hu FB. Changes in diet and lifestyle and long-term weight gain in women and men. *N Engl J Med*. 2011 Jun 23;364(25):2392-2404.

Reviews of Note ...

- Morley JE, ed. Geriatric medicine. Med Clin N Am. 2011 May;95(3):427-646. [12 articles]
- Järvinen KM. Food-induced anaphylaxis. Curr Opin Allergy Clin Immunol. 2011 Jun;11:255-261.
- Wechsler LR. Intravenous thromolytic therapy for acute ischemic stroke. N Engl J Med. 2011 Jun 2;364(22):2138-2146.
- Howes M-J R, Perry E. The role of phytochemicals in the treatment and prevention of dementia. Drugs Aging. 2011 Jun 1;28(6):439-468.
- Petersen RC. Mild cognitive impairment. N Engl J Med. 2011 Jun 9;364(23):2227-2234.
- Barrons R, Pegram A, Borries A. Inhaler device selection: Special considerations in elderly patients with chronic obstructive pulmonary disease. Am J Health-Syst Pharm. 2011 Jul 1;68:1221-1232.
- Rosen HR. Chronic hepatitis C infection. N Engl J Med. 2011 Jun 23;364(25):2429-2438.
- De Caterina R. n-3 fatty acids in cardiovascular disease. N Engl J Med. 2011 Jun 23;364(25):2439-2450.
- Abramowicz M, ed. Drugs for HIV infection. Treatment Guidelines. 2011 Jun;9(106):29-40.
- Abramowicz M, ed. Drugs for irritable bowel syndrome. Treatment Guidelines. 2011 Jul;9(107):41-46.

NEW RESOURCES in the DIC ...

- Sweetman S, ed. Martindale: The Complete Drug Reference. 2 vol. 37th ed. London: The Pharmaceutical Press, ©2011.



The last “dose” ...

Summer afternoon - summer afternoon; to me those have always been the two most beautiful words in the English language.

~Henry James [American writer, 1843 - 1916]



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