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Key Inforbits

- Three new drugs on the market
- Just one strength of acetaminophen solution
- Diabetic neuropathy guidelines issued
- AHA Scientific Statement on Triglycerides
- Alzheimer's diagnosis guidelines redefined
- ACCF/AHA Consensus on HTN in the elderly

NEW DRUGS, and other related stuff ...

New Drug ... (4/6/2011) The FDA has approved **vandetanib** (by AstraZeneca Pharmaceuticals; no trade name) for late-stage (metastatic) medullary thyroid cancer in adults who are ineligible for surgery and who have disease that is growing or causing symptoms. There are currently no FDA-approved treatments for this type of cancer. Vandetanib is administered orally, daily. Vandetanib's safety and effectiveness were established in a single, randomized international study of 331 patients with late-stage medullary thyroid cancer. Patients in the study received either vandetanib or placebo. Median progression-free survival was 16.4 months in the placebo arm and at least 22.6 months in the vandetanib arm. Common side effects included diarrhea, rash, nausea, high blood pressure, headache, fatigue, decreased appetite, and abdominal pain. Five deaths were reported; causes of death included breathing complications, heart failure, and sepsis. Vandetanib was shown to affect the electrical activity of the heart, which may cause irregular heart beats that could lead to death. Only health care professionals and pharmacies certified through the vandetanib REMS program, a restricted distribution program, will be able to prescribe and dispense the drug.

FDA approves new treatment for rare form of thyroid cancer. FDA News Release. 2011 Apr 6.

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm250168.htm>

New Drug ... (4/7/2011) The FDA has approved **gabapentin enacarbil (Horizant™ Extended Release Tablets)** by GlaxoSmithKline of Research Triangle Park, N.C., and Xenoport of Santa Clara, Calif.), a once-daily treatment for moderate-to-severe restless legs syndrome (RLS). The effectiveness of Horizant™ was studied in two 12-week clinical trials in adults. The trials showed an improvement in gabapentin enacarbil group compared with those taking a placebo. Horizant™ may cause drowsiness and dizziness and can impair a person's ability to drive or operate complex machinery. Gabapentin enacarbil becomes gabapentin, a drug used to treat seizures in people with epilepsy, when absorbed into the body. All drugs used to treat epilepsy carry warnings that they may cause suicidal thoughts and actions in a small number of people. Horizant™ will have the same warning.

FDA approves Horizant to treat restless legs syndrome. FDA News Release. 2011 Apr 7.

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm250188.htm>

New Drug ... (5/2/2011) The FDA has approved **linagliptin (Tradjenta™)** by Boehringer Ingelheim Pharmaceuticals Inc., Ridgefield, Conn., and Indianapolis-based Eli Lilly Co.) tablets,

used with diet and exercise, to improve blood glucose control in adults with Type 2 diabetes. Linagliptin blocks the enzyme dipeptidyl peptidase-4 or DPP-4, which leads to better blood glucose control. The drug was demonstrated safe and effective in eight double-blind, placebo-controlled clinical studies involving about 3,800 patients with Type 2 diabetes. Tradjenta™ will be dispensed with an FDA-approved Patient Package Insert that explains the drug's uses and risks. The most common side effects are upper respiratory infection, stuffy or runny nose, sore throat, muscle pain, and headache.

FDA approves new treatment for Type 2 diabetes. FDA News Release. 2011 May 2.

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm253501.htm>

APAP Solution Strength ... (5/4/2011) The Consumer Healthcare Products Association (CHPA), representing the makers of over-the-counter (OTC) single-ingredient liquid pediatric acetaminophen products has announced plans to convert these pediatric products to just one concentration. The transition should begin soon. This voluntary change means the current children's strength of liquid acetaminophen of 160 mg/5 mL will be the only liquid concentration available for all children under 12-years-old; concentrated infant drops will no longer be sold. It is important to note that during the transition, both concentrations of infants' acetaminophen liquid products will be available in stores and in medicine cabinets. The single-concentration liquid medicines will have additional enhancements to their age-appropriate dosing devices such as syringes for more accurate dosing and flow restrictors. Children's products, for ages two to under 12-years-old, will continue to offer dosing cups.

OTC Industry Announces Voluntary Transition to One Concentration of Single-Ingredient Pediatric Liquid Acetaminophen Medicines. Consumer Healthcare Products Association. 2011 May 4.

http://www.chpa-info.org/05_05_11_PedAceConv.aspx

FDA issues final guidance for liquid OTC drug products with dispensing devices. FDA PressRelease. 2011 May 4.

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm254029.htm>

FROM THE MEDICAL LITERATURE ...

Guidelines for diabetic neuropathy ... a joint effort of three associations, the American Academy of Neurology, American Association of Neuromuscular and Electrodiagnostic Medicine, and the American Academy of Physical Medicine and Rehabilitation. Some of the highlights include: Level A evidence stipulates that pregabalin should be offered for the treatment of painful diabetic neuropathy. Level B or C evidence includes anticonvulsants gabapentin and valproate should be considered for treatment. Antidepressants amitriptyline, venlafaxine, and duloxetine should be considered. Opioids dextromethorphan, morphine sulfate, tramadol, and oxycodone should be considered. Capsaicin or the Lidoderm patch may be considered. Nonpharmacologic methods such as electrical stimulation should be considered. Magnetic field treatment is not recommended.

Brill V, England J, Franklin GM, Backonja M, Cohen J, Del Toro D, Feldman E, Iverson DJ, Perkins B, Russel JW, Zochodne D. Evidence-based guideline: Treatment of painful diabetic neuropathy. Report of the American Academy of Neurology, American Association of Neuromuscular and Electrodiagnostic Medicine, and the American Academy of Physical Medicine and Rehabilitation. *Neurology*. 2011;76: 10.1212/WNL.0b013e3182166ebe.

<http://www.neurology.org/content/early/2011/04/08/WNL.0b013e3182166ebe.full.pdf+html>

AHA Scientific Statement on Triglycerides ... The new American Heart Association (AHA) statement includes an algorithm to screen/manage elevated triglycerides, and advises to use nonfasting levels for screening, at first. It is also important to rule out medications (eg, hormone therapy) and some conditions (eg, diabetes) as potential causes of high triglycerides. The AHA

has designated 100 mg/dL as the upper limit for "optimal" fasting triglycerides, but 150 mg/dL remains the cutoff for "elevated" levels. It is also stressed that 100 mg/dL is not a target for medical therapy, as studies have not shown the benefit of pharmacotherapy to reach this level. Miller M, Stone NJ, Ballantyne C, Bittner V, Criqui MH, Ginsberg HN, Goldberg AC, Howard WJ, Jacobson MS, Kris-Etherton PM, Lennie TA, Levi M, Mazzone T, Pennathur S; on behalf of the American Heart Association Clinical Lipidology, Thrombosis, and Prevention Committee of the Council on Nutrition, Physical Activity and Metabolism, Council on Arteriosclerosis, Thrombosis and Vascular Biology, Council on Cardiovascular Nursing, and Council on the Kidney in Cardiovascular Disease. Triglycerides and cardiovascular disease: a scientific statement from the American Heart Association. *Circulation*. 2011;123:xxx-xxx.

<http://circ.ahajournals.org/cgi/reprint/CIR.0b013e3182160726v1>

Alzheimer's diagnosis guidelines redefined ... from the working groups of the National Institute on Aging and the Alzheimer's Association, two notable differences from the Alzheimer's Disease criteria published in 1984 (over 25 years ago) are incorporation of biomarkers of the underlying disease state and formalization of different stages of disease in the diagnostic criteria. These new criteria could significantly increase the number of patients diagnosed with Alzheimer's.

http://www.alz.org/research/diagnostic_criteria/overview.asp (*Alzheimer's and Dementia: The Journal of the Alzheimer's Association*; 4 articles, in press, with the new criteria)

ACCF/AHA Consensus on hypertension in the elderly ... In the absence of evidence for treating hypertension in the elderly, the American College of Cardiology Foundation and the American Heart Association (in collaboration with other related societies) offer an expert consensus. In brief, the hypertension diagnosis is based on at least three measurements of blood pressure, taken on at least two separate office visits. The clinician should identify reversible or treatable causes, determine any organ damage, evaluate other cardiovascular risk factors, and identify barriers to treatment adherence. The treatment goal is <140/90 mm Hg. Treatment may consist only of lifestyle modification (eg, diet/sodium, weight, exercise). When drug therapy is called for, it should usually begin with a diuretic. When blood pressure is more than 20/10 mm Hg above goal, treatment should begin with a two-drug regimen. Octogenarians are approached less aggressively.

Aronow WS, Fleg JL, Pepine CJ, Artinian NT, Bakris G, Brown AS, Ferdinand KC, Forcica MA, Frishman WH, Jaigobin C, Kostis JB, Mancina G, Oparil S, Ortiz E, Reisin E, Rich MW, Schocken DD, Weber MA, Wesley DJ. ACCF/AHA 2011 expert consensus document on hypertension in the elderly: a report of the American College of Cardiology Foundation Task Force on Clinical Expert Consensus Documents. *J Am Coll Cardiol* 2011;57:xxx-xx. doi:10.1016/j.jacc.2011.01.008

<http://content.onlinejacc.org/cgi/content/full/j.jacc.2011.01.008v1>

Reviews of Note ...

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- Frampton JE. Telmisartan: A review of its use in cardiovascular disease prevention. *Drugs*. 2011;71(6):651-677.
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- Chang C, Gershwin ME. Drug-induced lupus erythematosus: Incidence, management and prevention. *Drug Saf*. 2011;34(5):357-374.
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- Dery AS, Hamilton LA, Starr JA. Nebivolol for the treatment of heart failure. *Am J Health-Syst Pharm*. 2011 May 15;68:879-886.

NEW RESOURCES in the DIC ...

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- Generali J, Paxton LH. *Black Box Warnings: Study Guide 2011*. BlackBoxRX, LLC, ©2011.
- Higby GJ. *In Service to American Pharmacy: The Professional Life of William Proctor, Jr.* Tuscaloosa: University of Alabama Press, ©1992.
- Briggs GG, Freeman RK, Yaffe SJ. *Drugs in Pregnancy and Lactation*. 9th ed. Baltimore: Lippincott Williams & Wilkins/Wolters Kluwer Health, ©2011.



The last “dose” ...

I know God will not give me anything I can't handle. I just wish that He didn't trust me so much.

~Mother Teresa [1910 - 1997]



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