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Key Inforbits

- Arcapta™ Neohaler™ for COPD
- Xarelto® for DTV and PE
- Brilinta™ a new antiplatelet agent
- New 2011-2012 flu vaccine formulation
- Guidelines for use of contraception
- Football season is coming!

NEW DRUGS, and other related stuff …

New Drug … (7/1/2011) The FDA has approved **indacaterol inhalation powder (Arcapta™ Neohaler™** by Novartis Pharmaceuticals Corp. of East Hanover, N.J.) for the long term, once-daily maintenance bronchodilator treatment of airflow obstruction in people with chronic obstructive pulmonary disease (COPD) including chronic bronchitis and/or emphysema. Indacaterol is a new molecular entity in the beta$_2$-adrenergic agonist class that helps muscles around the airways of the lungs stay relaxed to prevent symptoms of COPD, such as wheezing and breathlessness. Indacaterol is not intended to treat asthma or sudden, severe symptoms of COPD. The safety and efficacy of Arcapta™ Neohaler™ was demonstrated in six confirmatory clinical trials that included 5,474 patients ages 40 and older with a clinical diagnosis of COPD. Those treated had a smoking history of at least one pack a day for 10 years and exhibited moderate-to-severe decreases in lung function. Arcapta™ Neohaler™ carries a boxed warning that long-acting beta$_2$ adrenergic agonists (LABA) increase the risk of asthma-related death. All LABAs, including Arcapta™ Neohaler™, should not be used in patients with asthma, unless used with a long-term asthma control medication. The most common side effects reported by those using Arcapta™ Neohaler™ include runny nose, cough, sore throat, headache and nausea.

FDA approves Arcapta Neohaler to treat chronic obstructive pulmonary disease. FDA News Release. 2011 Jul 1.
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm261649.htm

New Drug … (7/1/2011) The FDA has approved **rivaroxaban (Xarelto®** by Janssen Pharmaceuticals, Inc. of Raritan, NJ), a factor Xa inhibitor, to reduce the risk of blood clots, deep vein thrombosis (DVT), and pulmonary embolism (PE) following knee or hip replacement surgery. Xarelto® is a once daily tablet. Those undergoing a knee replacement should take the medication for 12 days and patients undergoing a hip replacement procedure should take it for 35 days. More than 6,000 patients undergoing hip or knee replacement surgery received Xarelto® in clinical studies. Among patients undergoing knee replacement surgery, 9.7% of those treated with Xarelto® had VTE compared with 18.8% of patients who received enoxaparin. In a study involving hip replacement surgery, 1.1% of patients who received Xarelto® had VTE compared with 3.9% of those who received enoxaparin. In another study of hip replacement patients, 2% of those treated with Xarelto® had VTE compared with 8.4% of those who received enoxaparin. The most common side effect observed was bleeding.

FDA approves Xarelto to reduce risk of blood clots after hip, knee replacements. FDA News Release. 2011 Jul 5.
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm261839.htm
http://www.xareltohcp.com/sites/default/files/pdf/xarelto_0.pdf (full prescribing information)

New Drug … (7/20/2011) The FDA has approved **ticagrelor (Brilinta™** by AstraZeneca of Wilmington, Del.) to reduce cardiovascular death and heart attack in patients with acute coronary syndromes (ACS). Ticagrelor is a P2Y12 platelet inhibitor that prevents the formation of new blood clots, thus maintaining blood flow to help reduce the risk of another cardiovascular event. Ticagrelor has been studied in combination with aspirin. A boxed warning to health care professionals and patients warns that aspirin doses above 100 mg/day decrease medication effectiveness. The boxed warning also says that, like other antiplatelet agents, ticagrelor increases the rate of bleeding and can cause significant, sometimes fatal, bleeding. The most common adverse reactions reported in clinical trials were bleeding and dyspnea. Brilinta™ was approved with a Risk Evaluation and Mitigation Strategy (REMS), to help ensure that the drug's benefits outweigh its risks. As part of that plan, the company must conduct educational outreach to physicians to alert them about the risk of using higher doses of aspirin. In addition, Brilinta™ will be dispensed with a Medication Guide for patients. The guide will be distributed each time a patient fills their prescription.

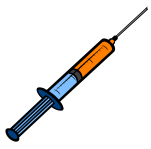
FDA approves blood-thinning drug Brilinta to treat acute coronary syndromes. FDA News Release. 2011 Jul 20.
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm263964.htm
http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/022433s000lbl.pdf (Package Insert)

Labeling Change … **for quetiapine (Seroquel®)** … (June 2011) from the revised package insert: "5.12 QT Prolongation : In clinical trials quetiapine was not associated with a persistent increase in QT intervals. However, the QT effect was not systematically evaluated in a thorough QT study. In post marketing experience, there were cases reported of QT prolongation in patients who overdosed on quetiapine [see Overdosage (10.1)], in patients with concomitant illness, and in patients taking medicines known to cause electrolyte imbalance or increase QT interval [see Drug Interactions (7)]. The use of quetiapine should be avoided in combination with other drugs that are known to prolong QTc including Class 1A antiarrythmics (e.g., quinidine, procainamide) or Class III antiarrythmics (e.g., amiodarone, sotalol), antipsychotic medications (e.g., ziprasidone, chlorpromazine, thioridazine), antibiotics (e.g., gatifloxacin, moxifloxacin), or any other class of medications known to prolong the QTc interval (e.g., pentamidine, levomethadyl acetate, methadone). Quetiapine should also be avoided in circumstances that may increase the risk of occurrence of torsade de pointes and/or sudden death including (1) a history of cardiac arrhythmias such as bradycardia; (2) hypokalemia or hypomagnesemia; (3) concomitant use of other drugs that prolong the QTc interval; and (4) presence of congenital prolongation of the QT interval. Caution should also be exercised when quetiapine is prescribed in patients with increased risk of QT prolongation (e.g. cardiovascular disease, family history of QT prolongation, the elderly, congestive heart failure and heart hypertrophy)."

Seroquel XR quetiapine fumarate extended release tablets. Package insert, AstraZeneca, Wilmington, DE. July 2011. http://www1.astrazeneca-us.com/pi/seroquelxr.pdf

FROM THE MEDICAL LITERATURE …

2011-2012 Flu Vaccine … The FDA has announced that the components of influenza vaccine for the 2011-2012 season will remain unchanged from those in the previous season's vaccine, and will include:



-- A/California/7/09 (H1N1)-like virus (the 2009 pandemic virus);
-- A/Perth /16/2009 (H3N2)-like virus; and
-- B/Brisbane/60/2008-like virus.

In addition, in May the FDA approved a new dose form, Fluzone Intradermal for patients aged 18 to 64 years. Also, just FYI, Dr. Karen Midthun of the FDA emphasizes the **importance of getting vaccinated every year**, even if the vaccine strains do not change, because of diminishing protection from the previous year.

FDA approves vaccines for the 2011-2012 influenza season. FDA News Release. 2011 Jul 18.
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm263319.htm

Medical Eligibility Criteria for Contraception … The Centers for Disease Control and Prevention (CDC) has created U.S. Medical Eligibility Criteria for Contraceptive Use, 2010, from guidance developed by the World Health Organization (WHO). It gives recommendations for the use of specific contraceptive methods by women and men based on certain characteristics or medical conditions. Most of the CDC guidance does not differ from the WHO document and covers over 60 characteristics or medical conditions; a few were modified for use in the U.S. and some were added. These recommendations are intended to assist health-care providers when they counsel women, men, and couples about contraceptive method choice. These recommendations serve as clinical guidance, but health-care providers should always consider the individual clinical circumstances for family planning services. The second citation provides an update to these criteria specifically for use of contraception during the postpartum period.

U.S. medical eligibility criteria for contraceptive use, 2010: Adapted from the World Health Organization medical eligibility criteria for contraceptive use, 4th ed. MMWR. 2011 Jun 18;59(RR-4):1-88.
http://www.cdc.gov/mmwr/pdf/rr/rr5904.pdf

Update to the CDC's U.S. Medical Eligibility Criteria for Contraceptive Use, 2010: Revised recommendations for the use of contraceptive methods during the postpartum period. MMWR 2011 Jul 8;60(26):878-883.
http://www.cdc.gov/mmwr/PDF/wk/mm6026.pdf

Take as directed? … from the *New York Times*, a physician is promoting the idea of standardizing prescription directions so that there are only four common times a medicine should be taken, morning, noon, evening and bedtime. This is not a new concept, but may be gaining some new traction. However, the more interesting aspect of this article is the discussion of the myriad ways a patient can interpret seemingly straightforward directions. This is particularly true when multiple medications are involved and it's a perspective pharmacists often lose. It's a short article, you should read it.

Span P. When 'Take as Directed' poses a challenge. New York Times. 2011 Jul 4.
http://www.nytimes.com/2011/07/05/health/views/05pills.html?_r=1&ref=health

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The last "dose" …

"Always remember... Goliath was a 40 point favorite over David."
James Ralph "Shug" Jordan [1910 -1980]

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