



Family Medicine Clinical Pharmacy Forum

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Family Medicine Clinical Pharmacy Forum is a brief bi-monthly publication from the Family Medicine clinical pharmacists distributed to faculty and residents of the Department of Family Medicine. Our intent is to provide timely information on broad-based issues of pharmacotherapy, as well as regulatory and practiced-based issues affecting you as a prescriber. If you have suggestions for things you would like to see, please contact us.

Pharmacotherapy Issues.

New Medication: The first inhaled insulin (*Exubera*) was approved January 27, 2006 by the US Food and Drug Administration (FDA) for the treatment of adult patients with type 1 and type 2 diabetes. It is a dry powder of recombinant insulin. The device that administers the insulin is the size of a standard flashlight.

Exubera is not to be used by smokers or people who have quit smoking within the previous 6 months. It is also not recommended for people with asthma, bronchitis, or emphysema. However, people with colds or other upper respiratory infection should still be able to take the drug, although it may cause coughing.

The FDA recommends pulmonary function testing prior to starting inhaled insulin and then every 6 to 12 months thereafter.

The drug is approved for treatment of both type 1 and type 2 diabetes. However, clinical trials found that fewer than 30% of people with type 1 diabetes were able to reduce their blood sugar to recommended levels after 6 months of treatment with the inhaled insulin.

Pfizer and Sanofi-Aventis did not seek FDA approval for Exubera in children and teenagers. Early trials in children were stopped due to concerns about Exubera's effects on children's breathing.

On the horizon... Two new medications are expected to be available this year for attention deficit/ hyperactivity disorder (ADHD):

Sparlon[®] is a reformulation of modafinil (*Provigil*[®]), which is indicated for treating excessive sleepiness associated with narcolepsy, obstructive sleep apnea/ hypopnea syndrome, and shift work sleep disorder. The differences in formulation between the two products are the type of tablet and the available strengths. *Provigil*[®] is a capsule-shaped, uncoated tablet available in 100 mg or 200 mg strengths. *Sparlon* is expected to be a small, film-coated tablet available in 85 mg, 170 mg, 255 mg, 340 mg, and 425 mg strengths to allow for individualized dosing when titrating for tolerability and efficacy.

Daytrana[®] is the second medication. It is a methylphenidate transdermal system that will be available in four strengths: 1.1 mg/hour, 1.78 mg/hour, 2.21 mg/hour, or 2.97 mg/hour. The patch is to be applied for nine hours and has a 12-hour duration of action. In clinical trials, the incidence of adverse effects (including: insomnia, decreased appetite, tics, and skin sensitization by the patch) were higher in the Daytrana treatment group. The patch was applied for 12 hours in clinical trials, due to the notable increased adverse effects, the manufacturer reduced the duration of wearing the patch to 9 hours. It appears that the incidence of the reported adverse effects will be lower with the shorter duration of

Authored and edited by:

Laurie Schenkelberg, Pharm.D.; with contributions by Nicholas Howell, Pharm.D. student and Rick Van Cleve, Pharm.D. student

East Des Moines Family Care Center



application. It is also recommended that oral methylphenidate should remain first line, with the patch reserved only in persons that are unable to swallow the tablets.

-Pharmacist Letter 2006;22:12.

Practice-Based Issues.

New Adverse Drug Report: Ketek (telithromycin) is an antibiotic in a new class, the ketolides. The mechanism of action resembles that of the macrolide antibiotics. It is recommended for the treatment of community acquired pneumonia (mild to moderate), including multi-drug resistant *Strep pneumoniae*. It is also indicated for the treatment of acute bacterial sinusitis and bacterial exacerbations of chronic bronchitis. *Annals of Internal Medicine* recently published an on-line article reporting three patients who experienced serious liver toxicity following administration of Ketek (telithromycin). All three patients developed jaundice and abnormal liver function tests. One patient recovered, one required a liver transplant, and one died. All three patients were previously healthy and were not using other prescription drugs. While it is difficult to determine the actual frequency of adverse events from voluntary reporting systems such as the MedWatch program, the FDA is continuing to evaluate the issue of liver problems in association with use of telithromycin in order to determine if labeling changes or other actions are warranted. It has also been reported to prolong the QTc interval, which places the patients at risk for ventricular arrhythmias. It should be avoided in patients with prolonged QTc intervals and patients that are on other medications that may also prolong the QTc interval.

<http://www.fda.gov/cder/drug/advisory/telithromycin.htm>

<http://www.acponline.org/journals/annals/hepatotoxicity.htm>

Amantadine Resistance in Influenza A (H3N2): The CDC is now warning NOT to use amantadine and rimantadine to prevent or treat influenza this year. Of the 123 influenza A isolates tested since October 2005, 91% have demonstrated resistance to these antivirals, up from only 11% last year. All isolates have remained susceptible to *Tamiflu* (oseltamivir) and *Relenza* (zanamivir).

Tamiflu is indicated for treatment or prophylaxis of patients as young as age 1. *Relenza* is indicated for treatment of patients age 7 and up. *Relenza* should not be given to patients with asthma or COPD.

-Pharmacist's Letter 2006;22:7.

-MMWR 2006;55(Dispatch):1-2.

New Plan B[®] Recommendations

Last month, the American College of Obstetrics and Gynecology changed its recommendations for the use of Plan B[®] for emergency contraception. Studies from the World Health organization, Canada, and a trial involving sites in the United Kingdom and Des Moines, Iowa, have all reported the efficacy of using levonorgestrel up to 120 hours after unprotected sex. Although Plan B[®] is more effective the sooner it is taken; the studies showed that it was still efficacious when used on days 4 and 5 compared to controls. ACOG previously recommended 72 hours for the limit of use of Plan B[®] for emergency contraception, but after review of these studies it now recommends use up to 120 hours.

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Plan B[®] consists of two 0.75mg levonorgestrel tablets. Although originally dosed as one tablet immediately and the second tablet taken 12 hours later, the WHO study also showed that taking both tablets as a single dose was just as effective as the divided dose regimen. Therefore, ACOG now recommends the single dose regimen.

-www.acog.org

-Obstet Gynecol 2003;101:1168-71.

New recommendations for pertussis immunizations:

Infant/childhood vaccination has contributed to a reduction of more than 90% in pertussis-related morbidity and mortality since the early 1940s in the United States. Estimates of childhood vaccination coverage with ≥ 3 doses of pertussis-containing vaccine have exceeded 90% since 1994; however, reported pertussis cases increased from a historic low of 1,010 in 1976 to 11,647 cases in 2003. A substantial increase in reported cases has occurred among adolescents, who become susceptible to pertussis approximately 6-10 years after childhood vaccination (immunity from the childhood vaccine wanes after 5 to 10 years). There are a couple of new tetanus, diphtheria, and acellular pertussis vaccines. *Boostrix* is indicated for ages 10 to 18 and *Adacel* for ages 11 to 64.

Adacel or *Boostrix* can be given if it has been ≥ 5 years for adolescents or ≥ 10 years for adults since the last tetanus-diphtheria booster. The reason to vaccinate adolescents and adults is two-fold: to reduce the morbidity of pertussis infection in the adolescent/adult population and to reduce the transmission of the infection to young infants who have not yet completed the primary immunization series. The most recent immunization guidelines in the United States recommend vaccination against tetanus, diphtheria, and pertussis in adolescents 11 to 12 years of age who have completed the recommended childhood vaccination series and have not received a tetanus and diphtheria toxoids (Td) booster dose. They also recommend immunizing adolescents 13 to 18 years of age who did not receive a booster dose of Td. The United States guidelines recommend at least a five-year interval from the last Td dose when a tetanus, diphtheria, and acellular pertussis vaccine product is used as a booster dose in adolescents (ten years or more for adults) to minimize the risk of local and systemic adverse reactions. However, for both adults and adolescents, Tdap may be given at shorter intervals (i.e., approximately two years) after Td, if needed. People over the age of ten years of age should receive only a single dose of *Adacel* or *Boostrix*. There is currently no recommendation to repeat the dose in the future. Subsequent Td boosters are recommended every ten years.

- Pharmacist's Letter 2006;22:11.

-http://www.cdc.gov/nip/vaccine/tdap/tdap_child_recs.pdf

Regulatory Issues.

Paroxetine in Pregnancy: UPDATE: Pregnancy class has been changed to Class D

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