



Rx TWO PHARMACY SERVICES, INC.

MEDICATION NEWSLETTER

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Medicare & CMS News

CMS has entirely revised the Unnecessary Medication Guidelines (F329) including clarifications of several aspects of medication management and a new medication table page that includes medications that are problematic to the nursing home population. For Pharmacy Services, regulatory guidance presently at Tags F425-431 have been combined into three remaining tags: F425 Pharmacy Services, F425 Drug Regimen Review, and F431 Labeling and Storage of Drugs and Biologicals. The new guidance speaks to the provision of pharmaceutical services for the entire distribution system, from ordering and acquisition to administration and disposal of medications to assure a safe system for each resident. These new guidelines went into effect December 18, 2006. The full text of these documents can be accessed on the ASCP Web site at: <http://www.ascp.com/som>

New FDA Approved Medications, Warnings, Indications, Formulations and News:

The FDA has approved Januvia (sitagliptin phosphate) tablets, the first diabetes treatment approved in a new class of drugs known as DPP-4 inhibitors that enhances the body's own ability to lower elevated blood sugar. Januvia has been approved as monotherapy and as add-on therapy to either of two other types of oral diabetes medications, metformin or thiazolidinediones (TZDs), to improve blood sugar (glucose) control in patients with type 2 diabetes when diet and exercise is not enough. The recommended dose of JANUVIA is 100 mg once daily. Januvia should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis, as it would not be

effective in these settings. Januvia enhances a natural body system called the incretin system, which helps to regulate glucose by affecting the beta cells and alpha cells in the pancreas. Through DPP-4 inhibition, Januvia works only when blood sugar is elevated to address diminished insulin due to beta-cell dysfunction and uncontrolled production of glucose by the liver due to alpha-cell and beta-cell dysfunction. The novel mechanism of Januvia is glucose-dependent, responding to the presence of elevated glucose and resulting in the release of insulin and decrease of glucagon only when needed, thereby lowering the potential for hypoglycemia. The most common side effects in clinical studies were upper respiratory tract infection, sore throat, and diarrhea.

Sepracor Inc. announced that the FDA approved its New Drug Application for Brovana (arformoterol tartrate) Inhalation Solution 15 mcg (micrograms) as a long-term, twice-daily (morning and evening), maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema. Brovana is for use by nebulization only. Brovana is the first long-acting beta2-agonist to be approved as an inhalation solution for use with a nebulizer.

Nexium For Delayed-Release Oral Suspension is now approved for the treatment of GERD, including symptomatic gastroesophageal reflux disease, healing and maintenance of healing of erosive esophagitis (EE), and risk reduction of NSAID-associated gastric (stomach) ulcers. Each packet of Nexium For Delayed-Release Oral Suspension contains either 20 mg or 40 mg of esomeprazole, the same active ingredient used in Nexium Delayed-Release Capsules. The esomeprazole

granules and inactive granules used in this formulation are mixed with water to form a suspension and are given by oral, nasogastric or gastric administration. The new formulation of Nexium For Delayed-Release Oral Suspension will be available in the first quarter of 2007.

GlaxoSmithKline (GSK) and Flamel Technologies (FLML) announced FDA approval of once-a-day Coreg CR (carvedilol phosphate) extended-release capsules, for the treatment of three cardiovascular conditions: (1) Hypertension, (2) A heart attack that has reduced how well the heart pumps (known medically as post-myocardial infarction left ventricular dysfunction), (3) Mild to severe heart failure. COREG CR will utilize Flamel's proprietary Micropump technology, which controls the delivery of carvedilol helping to maintain appropriate amounts of medicine in the body over a 24-hour span. This technology allows COREG CR to be dosed once daily, in contrast to immediate-release COREG (carvedilol) tablets, which patients must take twice daily. COREG CR will be available in the first quarter of 2007.

The FDA announced the approval of Omnaris (ciclesonide) nasal spray, a new drug for the treatment of nasal symptoms associated with seasonal and perennial allergic rhinitis, commonly known as hay fever, in adults and children 12 years of age and older. Although the precise way Omnaris works is unknown, the drug is a corticosteroid. The most common side effects in clinical studies were headache, nosebleeds, and inflammation of the nose and throat linings.

The FDA has approved Invega (paliperidone) extended-release tablets for the treatment of schizophrenia. Paliperidone is the principal active metabolite of risperidone, a marketed drug for treating schizophrenia. Among the commonly reported adverse events were restlessness, extrapyramidal symptoms (movement disorders), rapid heart beat and sleepiness. Invega is a member of a class of drugs called atypical antipsychotics that have an increased rate of death compared with

placebo in elderly patients with dementia-related psychosis. Invega is not approved for dementia-related psychosis. The recommended dose of Invega is 6 mg per day, with a dose range of 3 mg to 12 mg per day, depending on patient need.

The FDA has approved Alaway (ketotifen fumarate ophthalmic solution 0.025%). Alaway, a multiple action eye anti-allergic is indicated for the temporary relief of itchy eyes and will be marketed over-the-counter. An estimated 40 million people cope with itchy eyes associated with pollen, ragweed, grass, animal hair and dander -- particularly during the spring and fall months. Unlike over-the-counter anti-itch eye drop products currently available, just one dose of Alaway offers eye itch relief within minutes and lasts up to 12 hours. Other over-the-counter products currently available offer no more than four hours of relief and require four doses per day. Alaway, with its unique property of being both an antihistamine and a mast cell stabilizer addresses itchy eyes, the number one complaint among eye allergy sufferers.

Generic Drug Approvals:

- Ondansetron (Zofran) Injection 4 mg/2 ml and 40 mg/20 ml vials and Ondansetron Injection Premixed, 32 mg/50 mL in 5 percent dextrose
- Ondansetron (Zofran) tablets, Orally Disintegrating Tablets and Solution
- Bupropion hydrochloride (Wellbutrin-XL) Extended-Release Tablets
- Oxybutynin-XL (Ditropan-XL) 5mg, 10mg

Rx Two Pharmacy Services, Inc. was formed by a group of dedicated and seasoned LTC pharmacy professionals with the goal of providing comprehensive pharmacy services for our contracted nursing centers and their residents by utilizing state of the art computer technology and good old fashioned hard work.

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