By Shari J. Lynn, MSN, RN

DRUG Watch

A DRUG FOR OBESITY IS NOW AVAILABLE OTC

- Orlistat should not be used by transplant recipients or people who don't need to lose weight.
- It can cause diarrhea, flatus with discharge, and oily evacuation.

Orlistat, a medication prescribed for obesity and sold under the trade name Xenical, now is available in an over-the-counter formulation marketed as Alli (the prescription product will continue to be available at the higher dose). It's recommended for use in adults 18 years of age and older but isn't intended for people who either have difficulty absorbing food or do not need to lose weight. Patients who've undergone organ transplantation shouldn't take it because of a possible interaction with immunosuppressant medication (specifically, cyclosporine). Use of the drug by patients taking anticoagulants or medication to treat diabetes or thyroid disease may not be appropriate, and an NP or a physician should be consulted before a patient starts taking it. Orlistat is dispensed in 60-mg capsules that can be taken as often as three times a day with each meal containing fat. For maximum effect, the drug should be used as part of a regimen that includes a low-calorie, low-fat diet and an exercise program. Because orlistat is a lipase inhibitor that decreases the intestinal absorption of dietary fats, it can have adverse gastrointestinal effects, including diarrhea, flatus with discharge, bowel urgency, oily evacuation, fecal incontinence, and abdominal pain; patients should be made aware of this. Also, because of the possibility that the drug will induce the loss of certain nutrients, patients taking orlistat should be instructed to take a multivitamin at bedtime.

U.S. Food and Drug Administration. *FDA news: FDA approves orlistat for over-the-counter use.* 2007 Feb 7. http://www.fda.gov/bbs/topics/NEWS/2007/NEW01557.html; Roche. *[Label information]: Xenical (orlistat) capsules.* 2007 Jan. http://www.rocheusa.com/products/xenical/pi.pdf.

AN ASTHMA DRUG AND ANAPHYLAXIS: A STRONGER WARNING

- Anaphylaxis tends to occur within two hours but may occur as long as 24 hours after administration.
- Anaphylaxis can occur even after a patient has used the drug many times.

The Food and Drug Administration (FDA) has asked the manufacturer of omalizumab (Xolair) to add a black box warning to the labeling. The drug, which is taken for asthma caused by allergies, has been associated with anaphylaxis. The FDA has also requested that a medication guide be included with the packaging. Omalizumab was approved in 2003 for the treatment of adults and adolescents (12 years of age or older) with moderate-to-severe persistent asthma attributable to allergy to pollen, grass, or dust in whom inhaled steroids don't work well.

At the time omalizumab was approved, anaphylaxis had been identified as a possible adverse effect (on the basis of three cases identified in 3,507 patients involved in clinical trials, an incidence of approximately one in 1,000, although retrospective analysis revealed two additional cases). In the 48 postmarketing cases of anaphylaxis after the use of omalizumab reported between June 2003 and December 2005, two issues raised significant concern: first, while most (71%) occurred within the first two hours of administration, 13% occurred as long as 24 hours afterward; second, in a majority of cases (56%), anaphylaxis first occurred after repeated administration, sometimes after two years of treatment with the drug.

Nurses should be prepared for medication-related life-threatening emergencies after the administration of omalizumab. The drug should be administered in a clinician's office and the patient carefully observed for at least two hours for dizziness, labored breathing, tightness of the chest, syncope, hives and itching, and swelling of the mouth and throat, and emergency medication and equipment should be close at hand. Education provided to patients should include guidance in the recognition of the symptoms of anaphylaxis, and they should be given an epinephrine autoinjector (the EpiPen, for example) in case of a later reaction.

U.S. Food and Drug Administration. *FDA news: FDA proposes to strengthen label warning for Xolair.* 2007 Feb 21. http://www.fda.gov/bbs/topics/NEWS/2007/NEW01567.html; U.S. Food and Drug Administration. *Information for healthcare professionals: Omalizumab (for subcutaneous use) (marketed as Xolair).* 2007 Feb. http://www.fda.gov/cder/drug/InfoSheets/HCP/omalizumabHCP.pdf.

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FURTHER REVISIONS TO THE LABELING OF TELITHROMYCIN

- The FDA has rescinded two of the three previously approved indications for the antibiotic telithromycin.
- The drug packaging will include a new black box warning concerning the exacerbation of myasthenia gravis.

For the second time in a year, the Food and Drug Administration has announced revisions to the labeling of the ketolide antibiotic telithromycin (Ketek) (see *Drug Watch*, October 2006). Two of the three formerly approved indications have been rescinded: it's no longer approved for the treatment of either acute bacterial sinusitis or acute bacterial exacerbations of chronic bronchitis. The annulment of the indications was precipitated by the recommendation that emerged from a joint meeting of the Anti-Infective Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee held on December 14 and 15, 2006. At that meeting it was concluded that the balance between the risks and benefits of the drug no longer supports the agency's approval of the two uses because of case reports of rare but sometimes fatal hepatoxicity (including liver failure) and subsequent reports of drug-related adverse events, including disturbances of vision and loss of consciousness.

Telithromycin is still approved for the treatment of mild-to-moderate community-acquired pneumonia. However, because of reports of both life-threatening and fatal cases of respiratory failure of rapid onset and progression in patients with myasthenia gravis who took the drug, a new black box warning states that it is contraindicated in that population. The revised warning section advises of the risks of visual disturbances and loss of consciousness, in addition to the warning of hepatotoxicity that was already strengthened in June 2006. A medication guide for patients will also be developed.

Nurses should include information on the risks associated with the use of telithromycin in the education provided to patients and instruct patients to read the medication guide carefully.

U.S. Food and Drug Administration. *FDA news: FDA announces label and indication changes for the antibiotic Ketek*. 2007 Feb 12. http://www.fda.gov/bbs/topics/NEWS/2007/NEW01561.html; Center for Drug Evaluation and Research. U.S. Food and Drug Administration. *Revised label for Ketek (telithromycin) tablets*. Rockville, MD; 2007. http://www.fda.gov/cder/foi/label/2007/021144s012lbl.pdf.

ADHD MEDICATION: RISKS AND WARNINGS

- ADHD medications may increase the risks of serious cardiovascular and psychiatric events.
- The risks of cardiovascular events are even higher in children with heart disease.

Drugs used in the treatment of attention deficit–hyperactivity disorder (ADHD) have been associated with serious cardiovascular events and psychiatric symptoms. The Food and Drug Administration has asked the manufacturers of all ADHD drugs to create medication guides to inform consumers of those risks and of precautions they can take.

The decision was made after cases of serious cardiovascular events—stroke and heart attack in adults with certain risk factors, and sudden death in patients with underlying serious heart problems or defects—had been reported in patients taking ADHD medications at the recommended doses. The risks of both are considered to be further heightened in children with diagnosed (or undiagnosed) structural cardiovascular defects or cardiomyopathy.

In addition, there have been case reports of psychiatric events, including unwarranted suspicion, auditory hallucinations, and mania in patients with no psychiatric history. The agency's decision was also prompted by recommendations developed at the Drug Safety and Risk Management Advisory Committee meeting held in February 2006 and the Pediatric Advisory Committee meeting held in March; at the first, public testimony revealed widespread concern among parents whose children had died while taking a drug for ADHD that they had not received the full, appropriate information indicating that it could cause serious harm. The medication guides serve as an attempt to provide such information to consumers, but black box warnings will not be added to the labeling of the products at present. Committee recommendations also call for further research on the risks posed by ADHD medications.

It's imperative that a thorough health history, including cardiovascular risks and psychiatric problems, be obtained and recorded in the patient's medical record before the initiation of treatment with any ADHD drug. Nurses should assure parents that such adverse effects, while serious, appear to be rare and that the medications have been used safely in the vast majority of patients. Children treated with ADHD drugs have improved attention spans and perform better at school; their ability to interact with peers can also be improved by management of ADHD symptoms.

U.S. Food and Drug Administration. *FDA news: FDA directs ADHD drug manufacturers to notify patients about cardiovascular adverse events and psychiatric adverse events*. 2007 Feb 21. http://www.fda.gov/bbs/topics/NEWS/2007/NEW01568.html.

A PRODUCT IS APPROVED FOR USE IN VON WILLEBRAND DISEASE

- Antihemophilic factor–von Willebrand factor complex (human) is used in patients with von Willebrand disease who are undergoing surgery or other invasive procedures.
- It is approved for use only when desmopressin is either contraindicated or ineffective.

The Food and Drug Administration has approved antihemophilic factor–von Willebrand factor complex (human) (Alphanate) for use in patients with von Willebrand disease (types 1 and 2) who have to undergo invasive procedures or surgery. Von Willebrand disease, the most common inherited bleeding disorder, is caused by a deficiency in the von Willebrand factor (factor VIII in the clotting of blood, known also as the antihemophilic factor), which in normal clotting helps platelets aggregate and adhere to the blood vessel wall. Antihemophilic factor–von Willebrand factor complex (human) is purified from pooled human plasma from screened and tested U.S. donors and contains the clotting proteins that are either deficient or defective in patients with von Willebrand disease. Use of the drug has been shown to diminish the risk of bleeding during surgical procedures. It's already approved for the prevention and control of bleeding in surgical patients deficient in factor VIII secondary to hemophilia A or who have acquired factor VIII deficiency. It hasn't been approved for use in patients with severe von Willebrand disease (type 3) who need major surgery.

The first-line choice for managing surgery in patients with von Willebrand disease is desmopressin (DDAVP and others); the use of antihemophilic factor–von Willebrand factor complex (human) is restricted to those in whom desmopressin use is either ineffective or contraindicated.

Nurses working in the operating room should be aware of the use of antihemophilic factor–von Willebrand factor complex (human) and its possible adverse effects (itching, pharyngitis, paresthesia, headache, swelling of the face, and rash and chills).

U.S. Food and Drug Administration. *FDA news: FDA approves new product to treat von Willebrand disease.* 2007 Feb 2. http://www.fda.gov/bbs/topics/NEWS/2007/NEW01553.html. ▼