With rates of obesity and its many serious health consequences skyrocketing, consumers are turning to various weight loss methods, including diets, exercise plans, supplements, medications and surgery. At the time of this writing, one weight loss medication, orlistat (Xenical®), is being considered for over-the-counter (OTC) status under the trade name Alli. This article reviews the vital facts about orlistat and discusses the many questions its potential OTC status poses.

The Obesity Epidemic

Despite all the scientific progress that has been made in the areas of nutrition, fitness, and disease prevention and treatment, and despite the popularity of diets, rates of overweight and obesity have skyrocketed. More than 65 percent of U.S. adults are overweight or obese, raising the problem to epidemic proportions (Wilson, 2006).

The obesity epidemic is dramatically increasing the risk of coronary disease, stroke, diabetes, sleep apnea, cancer, hypertension, depression, osteoarthritis and other serious health problems. Obesity has become what U.S. Surgeon General, Richard Carmona, MD, calls the greatest threat to public health today (Wilson, 2006).

The Search for a “Magic Bullet”

Attempting to explain and reverse these trends is complex, difficult and often without clear answers. For some people, weight control seems to come easily, whereas for others, it’s a lifelong struggle. One thing is clear—the diet industry is booming, with people trying...
various diets, exercise regimes, behavior modification programs, medications and even surgery, often at a considerable financial and emotional expense.

In their efforts to find the magic fix, many people have turned to OTC (or over-the-Internet) herbals and other supplements, many of which lack Food and Drug Administration (FDA) approval or monitoring. In an effort to provide a more evidence-based OTC option for those needing to lose weight, the FDA agreed to consider the prescription weight loss drug orlistat (Xenical) for potential OTC status.

**Background on Orlistat**

Orlistat, a Roche Pharmaceutical product branded as Xenical since 1999, was developed for obesity management and to reduce risk of weight regain. The drug is minimally absorbed and is an inhibitor of lipase, an enzyme produced in the gastrointestinal tract that breaks down dietary fat. The resulting benefit for weight loss is that approximately 30 percent of the fat ingested is not broken down (and, thus, not absorbed). With this change, comes an increase in fecal fat excretion and predictable consequences that may include diarrhea, bloating, fecal urgency and fecal incontinence. Despite the unpleasant nature of the side effects, orlistat has been evaluated in more than 100 clinical trials and these adverse events are primarily nonserious and temporary (Jacob & Torgerson, 2005).

Maximum weight loss is expected at six months, which is the time target limit for treatment with the OTC product. Even though weight loss at one year may approximate only 5 percent, this may be clinically significant because that degree of weight loss has been shown in multiple studies to markedly reduce risk of many chronic diseases (Li et al., 2005; Ioannides-Demos, Proietto, & McNeil, 2005; Krempf et al., 2003).

**Alli: The OTC Version of Orlistat**

As the benefits and safety of use became more apparent, Roche began considering providing a nonprescription version of orlistat in addition to its prescription product, and, in 2004, GlaxoSmithKline licensed the right to the OTC version, to be called Alli (pronounced AL-eye), and began the application process for approval. In January 2006, the FDA Advisory Committee, in a vote of 11-3, favored approval of the drug for OTC use (GlaxoSmithKline Consumer Healthcare, L.P., 2006) and referred it on for a final decision by the FDA (which is undecided as of press time).

**What Nurses and Consumers Need to Know About OTC Orlistat**

There are various factors that nurses and consumers should be aware of regarding the use of OTC orlistat (Alli) for weight loss:

**Malabsorption concerns:** Although the drug is considered safe, the increased fat excretion it causes can lead to potential deficiencies in the absorption of fat-soluble nutrients (vitamins A, D, E and K). Because of this risk, it’s recommended that a supplemental multivitamin containing those vitamins be taken each day at least two hours before or after a dose of orlistat.

**Drug-drug interactions:** Because of the potential change in vitamin K status and the resulting potential for change in blood clotting, an indirect interaction exists between orlistat and warfarin, and careful monitoring of prothrombin times is essential with their concurrent use. Another substantial interaction exists with the posttransplant drug cyclosporine, leading to an estimated decrease in absorption of the latter by up to 30 percent or more; a two-hour dosing gap is recommended when the two are used together.

**Dosing guidelines:** The dosing for prescription orlistat is different from that for OTC orlistat. Prescription orlistat comes in 120-mg tablets, to be provided three times a day with meals, with each meal designed to include approximately 30 percent of calories from fat. Dosing with Alli is proposed to be one to two 60-mg tablets per meal, also with a target fat intake of 30 percent per meal, with a maximum dose of six tablets per day.

**Contraindications:** Clients with preexisting deficiencies in any of the fat-soluble vitamins and those with malabsorption disorders are advised not to use the drug. Other specific groups, however, have less clear guidelines: orlistat is an FDA category B drug for pregnancy (“not expected” to harm unborn

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Will clients be able to recognize possible related medical issues with orlistat use that are not yet known or easily recognized? For instance, a recent article proposed that a client’s itchy lesions on her feet, vulva and axillae may be related to use of the drug (Sergeant, Milne, & Shaffrali, 2006).

What effect will Alli have on blood sugar? Blood sugars in people with diabetes may change with the net reduced fat intake and weight loss; additional monitoring in these patients will be essential.

What effect could Alli have on transplant patients taking cyclosporine? Potential transplant patients are often required to lose weight in order to be considered for the surgery. One recent study indicated potential advantages of orlistat combined with a multidisciplinary weight management approach in helping clients reach weight goals for transplant (MacLaughlin et al., 2006). However, because of the drug interaction with the transplant drug cyclosporine, potential exists for unintentional reduced cyclosporine absorption if the client continues use of orlistat after transplant or in those transplant-failure clients who often continue use of cyclosporine.

What effect might Alli have in elderly patients? Vulnerable clients may include the elderly. In a recent online publication, the Senior Journal printed the following on the day after the FDA hearings: “Millions of senior citizens will join millions of others today in rejoicing at the news that a committee of the U.S. Food and Drug Administration has recommended approval of a popular prescription diet pill for OTC distribution” (Anonymous, 2006). Although the article did provide caveats that this pill was not a “magic bullet,” it did emphasize sensitive senior issues such as obesity’s relationship to higher health care costs, decreased life expectancy and decreased quality of life, implying a potential benefit to the use of orlistat to help prevent those issues.

Will Alli be used inappropriately by normal-weight individuals? Would Alli give normal-weight individuals a “license” to take the drug in order to eat high-fat foods with less guilt or in hopes of improving lipid profiles, knowing the fats would be less absorbed? Would they then begin to use the drug long term?

Will parents, desperate over the rapidly rising rate of childhood obesity, be tempted to give Alli to their children, even though it’s not approved for that use? Xenical was approved for use in overweight children ages 12 to 16 in 2003, but GlaxoSmithKline believes adolescent use should be restricted to the prescription setting. They propose to use age verification requirements at time of purchase (GlaxoSmithKline Consumer Healthcare, L.P., 2006).

In response to such concerns, GlaxoSmithKline is proposing comprehensive labeling and a 250-page “starter pack” for all users of Alli, to include a companion guide, healthy-eating guide, fat and calorie counter, daily journal, “quick facts” card and an offer of a free optional 12-month behavioral support program (available online or via direct mail).

Conclusions

Time will tell if Alli indeed hits the OTC market and what, if any, effect it has on the health and waistlines of perhaps millions of consumers. We all may wish for “the good old days,” when staying thin seemed simple and when one fix fit all. A weight-loss drug such as Alli, with all its potential side effects, would have seemed unheard of. But with the complexity of today’s global obesity problem, more than one approach will be essential in slowing down and/or reversing this epidemic. Nurses and other health care professionals need to know all the
facts and consider the needs of each individual patient.

One thing is for sure: If we, as health professionals, hide our heads in the sand in deference to how we’ve “always” treated obesity, our patients will go skipping right past traditional treatments to potentially far worse options on their own, and our motives, however well-intentioned, will be left in the dust of the expanding epidemic of obesity.

References
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