



alli (orlistat 60 mg capsules) Fact Sheet

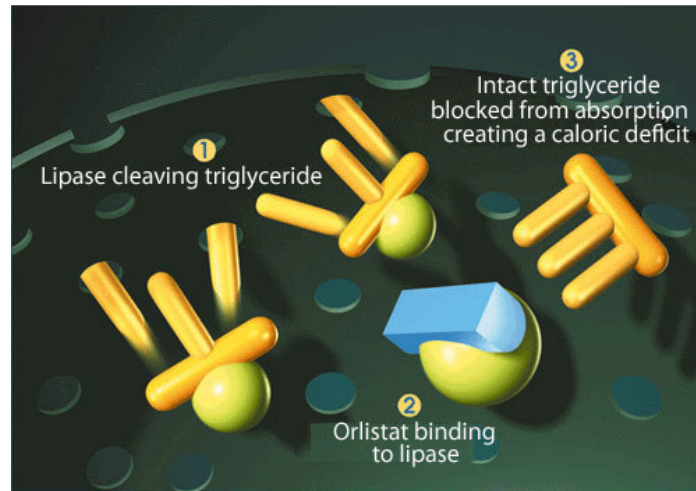
The only FDA-approved, over-the-counter, weight-loss product

- On February 7, 2007, the U.S. Food and Drug Administration (FDA) approved orlistat 60 mg capsules for over-the-counter (OTC) use in the United States. GlaxoSmithKline Consumer Healthcare will market OTC orlistat under the brand name alli™ (pronounced AL-eye).
- alli represents the only FDA-approved weight-loss product soon to be available to consumers without a prescription. alli is indicated for overweight adults 18 years and older taken in conjunction with a reduced-calorie, low-fat diet.
- alli is more than a pill; it's a comprehensive program that works in conjunction with a sensible diet to increase weight loss.
- alli is effective – it helps people lose 50 percent more weight than dieting alone. Instead of losing 10 pounds with a diet, add alli and you can lose 15.
 - Clinical studies support alli's ability to safely help people achieve meaningful (five percent) weight loss when used in conjunction with a reduced-calorie, low-fat diet.^{1,2}
 - Research has shown that as little as a five percent reduction in weight substantially improves health outcomes in obese people.³
- alli (60 mg orlistat capsules) is safe and effective when used as directed. As the most extensively studied weight-loss medication on the market, the safety and efficacy of orlistat is very well established. A higher dose of orlistat has been marketed as the prescription drug Xenical® (orlistat 120 mg capsules) in the U.S. since 1999 and is supported by nine years of worldwide use in 145 other countries.
 - Orlistat experience in more than 25 million patient treatments and more than 100 clinical studies with more than 30,000 patients is unprecedented.
 - One of these studies with Xenical is the four-year landmark XENDOS trial conducted by Roche, its inventor and manufacturer. This study is the longest study ever conducted for a weight-loss medicine.
- alli is not for everyone. It's for the consumer who can follow a reduced-calorie, low-fat diet for weight loss.

How alli Works

Unlike other weight loss products, alli is not an appetite suppressant and does not affect the brain or the central nervous system. Instead, it works in the digestive system to block about 25 percent of fat from being digested, making fewer calories available. The calorie deficit leads to weight loss.

GASTROINTESTINAL TRACT



When fat is consumed, the body breaks it down into its simplest components so it can be digested. Enzymes in the intestinal tract, called lipases, help with this process. Orlistat attaches to lipases and blocks them from breaking down about 25 percent of the dietary fat consumed. The undigested fat passes through the GI tract and is eliminated.⁴

Because of the way it works, Orlistat must be used in conjunction with a reduced-calorie, low-fat diet containing about 15 grams of fat per meal. Consuming a meal with too much fat while taking Orlistat can result in bowel changes such as having an urgent need to use the bathroom. These changes, called treatment effects, generally occur in the first weeks of treatment, are not harmful, and can be managed by sticking to the recommended diet with about 15 grams of fat per meal.

For more information, go to myOrlistat.com, where you will find an individualized online action plan.

¹ Hauptman J, Lucas C, Baldrin MN, Collins H, Segal K. "Orlistat in the long-term treatment of obesity in primary care settings." *Arch of Fam Med* 9:160-167.

² Rossner S, Sjostrom L, Noack R, Meidners AE, Nosedall G. "Weight loss, weight maintenance, and improved cardiovascular risk factors after 2 years treatment with Orlistat for obesity." *Obesity Research* 8:49-61, 2000.

³ Hauptman J, Lucas C, Baldrin MN, Collins H, Segal K. "Orlistat in the long-term treatment of obesity in primary care settings." *Arch of Fam Med* 9:160-167.

⁴ Patient Information for Xenical® (Orlistat) Capsules. Roche.