



**GENERIC NAME:** orlistat

**DRUG CLASS AND MECHANISM**

Orlistat is a drug that promotes loss of weight by preventing the digestion and absorption of fat in food. In the intestine, an enzyme called lipase (produced primarily by the pancreas) breaks apart fat in food so that it can be absorbed into the body. Orlistat blocks the action of lipase and thereby prevents the breakup and absorption of fat. Orlistat blocks absorption of about 25% of the fat in a meal. The unabsorbed fat is excreted in the stool. The FDA approved Orlistat by prescription in 1999. alli, a lower dose formulation of orlistat, was approved for purchase without a prescription "over the counter" in 2007.

**PRESCRIPTION:** Orlistat yes, alli no

**PREPARATIONS:** Capsules: 60 mg (alli), 120 mg (Xenical)

**STORAGE:** Capsules should be stored at room temperature, 15-30°C (59-86°F)

**PRESCRIBED FOR**

Orlistat is combined with a reduced-calorie diet to promote weight loss. Orlistat also may be used to prevent weight gain after weight has been lost. Candidates for treatment with orlistat are patients who are obese with a body mass index (a measure of obesity) of more than 30 kg/m<sup>2</sup>. Candidates also include patients with a body mass index of between 27 and 30 kg/m<sup>2</sup> if other risk factors for arteriosclerosis are present such as high blood pressure, diabetes, and elevated blood cholesterol or triglycerides. Based on several scientific studies, the average weight loss that is achieved when orlistat is taken as recommended for six months to one year is 12.4 to 13.4 pounds.

**DRUG INTERACTIONS**

The blood thinning effect of warfarin (Coumadin) depends on the amount of vitamin K in the body, and vitamin K is one of the vitamins that binds to fat. Patients receiving warfarin who begin orlistat should have their blood clotting monitored closely because the orlistat may cause levels of vitamin K to decline. This will increase the effects of warfarin and lead to abnormal bleeding from the warfarin. There is no evidence that a deficiency of vitamin K occurs in patients who are taking orlistat.

**USES**

This medication is used with a reduced-calorie diet to help significantly overweight persons lose weight. It also helps to prevent regaining weight previously lost. Orlistat works by blocking some of the fat normally digested by the intestine.

**HOW TO USE**

Take this drug by mouth, generally three times daily during (or up to one hour after) each main meal that contains fat. Your daily intake of fat, protein and carbohydrate should be evenly spread over three main meals. If a meal is occasionally missed or contains no fat, skip that dose of the medication. Because this drug can interfere with absorption of fat-soluble vitamins (e.g., A,D,E,K), a daily multivitamin supplement containing these nutrients is recommended. Take the multivitamin at least 2 hours before or 2 hours after this drug (e.g., at bedtime). The effects of this drug may begin as soon as 1-2 days after treatment begins; noticeable weight loss will take longer.

**PRECAUTIONS**

Tell your doctor your medical history, including: allergies, digestive disorders (malabsorption or cholestasis), low thyroid function (hypothyroidism), other metabolism problems (e.g., oxalate kidney stones, hyperoxaluria). This drug should not be used if you have anorexia nervosa or bulimia-type eating disorders. Tell your doctor if you are pregnant before using this medication. The manufacturer does not recommend use of this drug during pregnancy. It is not known whether this drug is excreted into breast milk. Because of the potential risk to the infant, breast-feeding while using this drug is not recommended. Consult your doctor before breast-feeding.

**SIDE EFFECTS**

The most common side effects of orlistat are oily spotting on underwear, flatulence, urgent bowel movements, fatty or oily stools, increased number of bowel movements, abdominal pain or discomfort, and inability to control stool

(incontinence). Between 1 in 250 and 1 in 70 patients experienced one or more of these symptoms in the first year. Generally, the side effects occurred within three months of starting therapy. In about 50% of patients, the side effects resolved within one to four weeks, but the effects in some patients lasted six months or longer. To reduce the occurrence of these side effects, meals should contain no more than 30% fat because it is the unabsorbed fat that causes most of the symptoms. alli causes fewer side effects because it contains half the dose of prescription-strength orlistat. Patients receiving orlistat with a history of oxalate kidney stones may develop increased levels of oxalate in their urine, which may increase the risk of kidney stones.

**DOSING**

The recommended prescription dose for Xenical is one capsule (120 mg) three times daily. The recommended dose for alli is 60 mg three times daily. Orlistat should be taken one hour after or during a meal containing about 15 mg of fat. Meals without fat do not require orlistat. No additional benefit has been shown when orlistat was taken in doses greater than 120 mg. Patients should eat a nutritionally balanced, reduced calorie diet that contains approximately 30% of calories from fat. alli includes an individually tailored online weight loss support program.

Some dietary vitamins bind to fat (vitamins A, D, E and beta- carotene). When orlistat is taken, these vitamins are not absorbed and are eliminated in the stool in increased amounts along with the fat. Therefore, patients taking orlistat should take a multivitamin containing these "fat-soluble" vitamins to ensure that adequate amounts of the vitamins are available for absorption. To ensure that the vitamins in the multivitamins are not bound to fat like the vitamins in the diet, the multivitamin should be taken at least two hours before or several hours after the orlistat.

**Orlistat** may reduce the absorption and blood levels of cyclosporine (Sandimmune) when both drugs are administered together. Therefore, cyclosporine should be administered two hours before or after orlistat, and more frequent monitoring of cyclosporine levels may be needed.

Hypothyroidism has been reported when orlistat and levothyroxine were combined. Patients treated with both orlistat and levothyroxine should be monitored for changes in thyroid function. The orlistat and levothyroxine should be taken at least four hours apart.

**OVERDOSE**

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly.

**MISSED DOSE**

If you miss a dose, use it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

**STORAGE**

Store at room temperature (77 degrees F, 25 degrees C) away from light and moisture.

**Note :** This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.



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