

Patient Information

XENICAL[®] (zen'i-cal)

(orlistat)

Capsules



Read this Patient Information before you start taking XENICAL and each time you get a refill. There may be new information. This information does not take the place of talking to your doctor about your medical condition or your treatment.

What is XENICAL?

XENICAL is a prescription medicine used with a low calorie diet to increase weight loss in people with obesity. XENICAL may help obese people lose weight and keep the weight off.

It is not known if XENICAL is safe and effective in children under 12 years old.

Who should not take XENICAL?

Do not take XENICAL if you:

- are pregnant. A minimum weight gain, and no weight loss, is currently recommended for all pregnant women, including those who are already overweight or obese.
- always have problems absorbing food (chronic malabsorption)
- have gallbladder problems (cholestasis)
- are allergic to orlistat or any of the ingredients in XENICAL. See the end of this leaflet for a complete list of ingredients in XENICAL

What should I tell my doctor before taking XENICAL?

Before you take XENICAL, tell your doctor about all of your medical conditions, including if you:

- have liver problems
- have kidney problems
- have problems with your thyroid
- have eating problems such as anorexia or bulimia
- have diabetes
- have a seizure disorder (epilepsy)
- have an abnormal heart rhythm (arrhythmia)
- have the human immunodeficiency virus (HIV)
- are breastfeeding or plan to breastfeed. It is not known if XENICAL passes into your breast milk. Talk to your doctor before you breastfeed and take XENICAL.
- are pregnant or plan to become pregnant. Do not take XENICAL if you are pregnant or plan to become pregnant.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

XENICAL and other medicines may affect each other causing side effects. XENICAL may affect the way other medicines work, and other medicines may affect the way XENICAL works.

Especially tell your doctor if you are taking:

- cyclosporine (Gengraf, Neoral, Sandimmune, Restasis, Sangcya)
- beta-carotene or vitamin E supplements
- levothyroxine (Levo-T, Levolet, Levothyroid, Levothyroxine Sodium, Levoxyl, Novothyrox, Synthroid, Tirosint, Unithroid).
- warfarin (Athrombin, Athrombin-K, Coumadin, Jantoven, Panwarfin, Warfarin Sodium)
- amiodarone (Cordarone, Pacerone)
- medicines used to treat seizures. They may not work as well while you take XENICAL. Talk to your doctor right away if your seizures happen more often or get worse while you take XENICAL.
- antiretroviral medicines used to treat HIV. They may not work as well while you take XENICAL.

Know the medicines you take. Keep a list of your medicines and show it to your doctor and pharmacist when you get a new medicine.

How should I take XENICAL?

- Take XENICAL exactly as your doctor tells you to take it.
- Your doctor will tell you how much XENICAL to take and when to take it.
- Take XENICAL with your meals or up to one hour after your meal. If you miss a meal or have a meal without fat, you can skip your dose of XENICAL. If you take a cyclosporine medicine, take XENICAL and cyclosporine at least 3 hours apart. **See “What should I tell my doctor before taking XENICAL?”** for a complete list of cyclosporine medicines.
- If you take a multivitamin, take it at least 2 hours before or after you take XENICAL. Bedtime is a good time to take your multivitamin.
- If you take a levothyroxine medicine, take XENICAL and levothyroxine at least 4 hours apart. **See “What should I tell my doctor before taking XENICAL?”** for a complete list of levothyroxine medicines.
- Take XENICAL with a nutritionally balanced, low calorie diet that has no more than about 30% of calories from fat. Taking XENICAL with any meal high in fat (more than 30% fat) may make the common side effects worse. **See Table 1.**

Table 1

| IF YOUR DAILY CALORIE LEVEL IS: | THE RECOMMENDED DAILY GRAMS OF FAT (in a 30% fat diet) ARE: |
|---------------------------------|---|
| 1500 | 50 |
| 1600 | 53 |
| 1800 | 60 |
| 2000 | 67 |

- If you take too much XENICAL call your doctor or go to the nearest hospital emergency room right away.

What are the possible risks of XENICAL? XENICAL may cause serious side effects, including:

- **Lowered absorption of certain vitamins in your body.** Take a multivitamin containing vitamins A, D, E, K, and beta-carotene one time each day. Take a multivitamin at least 2 hours before or after you take XENICAL, such as at bedtime.
- **Severe liver problems.** Stop taking XENICAL and call your doctor right away if you have the following symptoms of liver problems:
 - loss of appetite
 - itchy skin
 - yellowing of your skin or the white part of your eyes
 - amber-colored urine
 - light-colored bowel movements (stools)
 - pain in the upper right portion of your stomach
- **Kidney problems.** Your doctor may do certain tests to check your kidney function during treatment with XENICAL. Call your doctor right away if you have the following symptoms of kidney problems:
 - swelling, especially of the legs and feet
 - little or no urine output
 - frequent or painful urination
 - blood in the urine
 - loss of appetite, nausea and vomiting
 - severe pain in the back, belly or groin
- **Gallbladder problems (gallstones).** Call your doctor right away if you have the following symptoms of gallstones:
 - pain in the upper right portion of your stomach
 - nausea
 - vomiting

XENICAL[®]
(orlistat)
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XENICAL® (orlistat) Capsules

The most common side effects of XENICAL include:

- oily* rectal discharge
- passing gas with oily discharge*
- urgent need to have a bowel movement
- oily* or fatty stools
- increased number of bowel movements
- being unable to control your bowel movements

*Oily discharge may be clear or have an orange or brown color.

These are not all the possible side effects of XENICAL.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store XENICAL?

- Store XENICAL at 59°F to 86°F (15°C to 30°C).
- Keep XENICAL in a tightly closed container.
- Do not use XENICAL after the expiration date on the bottle.
- Safely throw away medicine that is out of date or no longer needed.

Keep XENICAL and all medicines out of the reach of children.

General information about the safe and effective use of XENICAL

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use XENICAL for a condition for which it was not prescribed. Do not give XENICAL to other people, even if they have the same symptoms that you have. It may harm them.

This Patient Information leaflet summarizes the most important information about XENICAL. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about XENICAL that is written for health professionals. For more information, call the Safety Call Center at 1-888-236-5445.

What are the ingredients in XENICAL?

Active Ingredient: orlistat

Inactive Ingredients: microcrystalline cellulose, sodium starch glycolate, sodium lauryl sulfate, povidone, talc, gelatin and titanium dioxide.

Turquoise capsule shell: FD&C Blue No. 2, with black printing ink containing pharmaceutical grade shellac, propylene glycol, strong ammonium solution, potassium hydroxide and black iron oxide.

Other Information: Body Mass Index

The chart below illustrates body mass index (BMI) according to a variety of weights and heights. XENICAL is intended for patients with a BMI of greater than or equal to 30 kg/m² or a BMI of greater than or equal to 27 kg/m² in the presence of other risk factors such as hypertension, diabetes, or high cholesterol. The BMI is calculated by dividing your weight in kilograms by your height in meters squared. To use this chart:

- Find the height closest to your height in the left-hand column.
- Then move across the top row to find the weight closest to your weight.
- The number where these two meet is your BMI. (For example, a person who weighs 180 lbs and is 5'5" has a BMI of 30.)

WEIGHT (lb)

| | 120 | 130 | 140 | 150 | 160 | 170 | 180 | 190 | 200 | 210 | 220 | 230 | 240 | 250 | 260 | 270 | 280 | 290 | 300 | 310 | 320 |
|-------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| 4'10" | 25 | 27 | 29 | 31 | 34 | 36 | 38 | 40 | 42 | 44 | 46 | 48 | 50 | 52 | 54 | 57 | 59 | 61 | 63 | 65 | 67 |
| 4'11" | 24 | 26 | 28 | 30 | 32 | 34 | 36 | 38 | 40 | 43 | 45 | 47 | 49 | 51 | 53 | 55 | 57 | 59 | 61 | 63 | 65 |
| 5'0" | 23 | 25 | 27 | 29 | 31 | 33 | 35 | 37 | 39 | 41 | 43 | 45 | 47 | 49 | 51 | 53 | 55 | 57 | 59 | 61 | 63 |
| 5'1" | 23 | 25 | 27 | 28 | 30 | 32 | 34 | 36 | 38 | 40 | 42 | 44 | 45 | 47 | 49 | 51 | 53 | 55 | 57 | 59 | 61 |
| 5'2" | 22 | 24 | 26 | 27 | 29 | 31 | 33 | 35 | 37 | 38 | 40 | 42 | 44 | 46 | 48 | 49 | 51 | 53 | 55 | 57 | 59 |
| 5'3" | 21 | 23 | 25 | 27 | 28 | 30 | 32 | 34 | 36 | 37 | 39 | 41 | 43 | 44 | 46 | 48 | 50 | 51 | 53 | 55 | 57 |
| 5'4" | 21 | 22 | 24 | 26 | 28 | 29 | 31 | 33 | 34 | 36 | 38 | 40 | 41 | 43 | 45 | 46 | 48 | 50 | 52 | 53 | 55 |
| 5'5" | 20 | 22 | 23 | 25 | 27 | 28 | 30 | 32 | 33 | 35 | 37 | 38 | 40 | 42 | 43 | 45 | 47 | 48 | 50 | 52 | 53 |
| 5'6" | 19 | 21 | 23 | 24 | 26 | 27 | 29 | 31 | 32 | 34 | 36 | 37 | 39 | 40 | 42 | 44 | 45 | 47 | 49 | 50 | 52 |
| 5'7" | 19 | 20 | 22 | 24 | 25 | 27 | 28 | 30 | 31 | 33 | 35 | 36 | 38 | 39 | 41 | 42 | 44 | 46 | 47 | 49 | 50 |
| 5'8" | 18 | 20 | 21 | 23 | 24 | 26 | 27 | 29 | 30 | 32 | 34 | 35 | 37 | 38 | 40 | 41 | 43 | 44 | 46 | 47 | 49 |
| 5'9" | 18 | 19 | 21 | 22 | 24 | 25 | 27 | 28 | 30 | 31 | 33 | 34 | 36 | 37 | 38 | 40 | 41 | 43 | 44 | 46 | 47 |
| 5'10" | 17 | 19 | 20 | 22 | 23 | 24 | 26 | 27 | 29 | 30 | 32 | 33 | 35 | 36 | 37 | 39 | 40 | 42 | 43 | 45 | 46 |
| 5'11" | 17 | 18 | 20 | 21 | 22 | 24 | 25 | 27 | 28 | 29 | 31 | 32 | 34 | 35 | 36 | 38 | 39 | 41 | 42 | 43 | 45 |
| 6'0" | 16 | 18 | 19 | 20 | 22 | 23 | 24 | 26 | 27 | 29 | 30 | 31 | 33 | 34 | 35 | 37 | 38 | 39 | 41 | 42 | 43 |
| 6'1" | 16 | 17 | 19 | 20 | 21 | 22 | 24 | 25 | 26 | 28 | 29 | 30 | 32 | 33 | 34 | 36 | 37 | 38 | 40 | 41 | 42 |
| 6'2" | 15 | 17 | 18 | 19 | 21 | 22 | 23 | 24 | 26 | 27 | 28 | 30 | 31 | 32 | 33 | 35 | 36 | 37 | 39 | 40 | 41 |

This Patient Information has been approved by the U.S. Food and Drug Administration.

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