

1 TO PHARMACIST: PLEASE PROVIDE THIS INFORMATION TO THE PATIENT.  
2



4 **Important Patient Information**

5 **Patient Information about XENICAL (orlistat) Capsules**

6 **XENICAL (zen' i-cal)**

7 **Generic Name: orlistat**

8 **R<sub>x</sub> only**

9 Please read this information before you start taking XENICAL and each time you renew  
10 your prescription. This important information may help you successfully lose weight and  
11 maintain your weight loss while taking XENICAL. This patient information is a  
12 summary and is not intended to take the place of discussions with your doctor. It does not  
13 list all benefits and risks of XENICAL. The medication described here can only be  
14 prescribed and dispensed by a licensed health care professional, who has information  
15 about your medical condition and more information about the drug, including how to take  
16 it, what to expect, and potential side effects. If you have any questions about XENICAL,  
17 talk with your doctor.

18 **What is XENICAL?**

19 XENICAL is an oral prescription weight loss medication used to help obese people lose  
20 weight and keep this weight off. XENICAL works in your intestines, where it blocks  
21 some of the fat you eat from being absorbed. This undigested fat is then eliminated in  
22 your bowel movements. XENICAL should be used together with a reduced-calorie diet  
23 that your doctor will recommend.

24 Excess weight has been proven to contribute to an increased risk of developing many  
25 medical problems, including high blood pressure, high cholesterol, heart disease, and  
26 diabetes. The consumption of excess fatty food and calories plays a significant role in the  
27 development of excess weight. While fat is an important component of a balanced diet,  
28 the consumption of excess fat contributes to excess body weight, since fat provides twice  
29 the number of calories per gram of weight as carbohydrates and protein. Reduction of  
30 dietary fat intake is one potential way of losing weight.

31 **How does XENICAL work?**

32 If you eat an excess amount of fat or calories, the excess is stored as fat by the body  
33 resulting in weight gain. When you eat fat, your body breaks it down into its simplest  
34 components so that it can be absorbed. Enzymes in your intestinal tract, called lipases,  
35 help digest (or break down) fat. When you take XENICAL with meals, XENICAL  
36 attaches to the lipases and blocks them from breaking down some of the fat you have  
37 eaten. The undigested fat cannot be absorbed and is eliminated in your bowel  
38 movements. By working this way, XENICAL helps block about 30% of the fat eaten in  
39 food from being absorbed by your body.

40 **Information for adult obese patients**

41 Following one year of treatment, XENICAL in combination with diet was shown to be  
42 more effective in reducing weight than diet alone. In most cases, weight loss was gradual.  
43 Patients treated with XENICAL and a reduced-calorie diet for one year lost an average of  
44 13.4 pounds while those on a reduced-calorie diet alone lost 5.8 pounds.

45 **Information for adolescent obese patients**

46 Following one year of treatment, XENICAL in combination with diet was shown to be  
47 more effective in reducing Body Mass Index (BMI) than diet alone. A reduction in Body  
48 Mass Index is a better indicator of weight loss in children because it takes into account  
49 changes in weight related to growing children.

50 **Who should use XENICAL?**

51 A weight loss program that includes a reduced-calorie diet and appropriate physical  
52 activity may be adequate in some patients. You should discuss with your doctor or other  
53 health care provider whether XENICAL should be added to such a program.

54 XENICAL may be right for you if you are considerably overweight (at least 30% above  
55 ideal weight or a body mass index of 30 or greater). XENICAL may also be right for you  
56 if you are overweight (at least 20% above ideal weight or a body mass index of 27 or  
57 greater) and also have other risk factors such as high blood pressure, high cholesterol,  
58 heart disease, or diabetes.

59 **How to determine your body mass index (BMI):**

60 The chart below illustrates BMI according to a variety of weights and heights. The BMI  
61 is calculated by dividing your weight in kilograms by your height in meters squared. To  
62 use this chart:

- 63 • Find the height closest to your height in the left-hand column.  
64 • Then move across the top row to find the weight closest to your weight.  
65 • The number where these two meet is your BMI. (For example, a person who weighs  
66 180 lbs and is 5'5" would have 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
HEIGHT (ft/in)	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	

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### 70 **Who should not use XENICAL?**

71 Those who:

- 72 • consistently have problems absorbing food (chronic malabsorption); or
- 73 • have gallbladder problems; or
- 74 • are pregnant or are breastfeeding a child; or
- 75 • have ever had an allergic reaction to orlistat or any of the inactive ingredients in
- 76 XENICAL.

### 77 **What should I tell my doctor before taking XENICAL?**

78 Before beginning treatment with XENICAL, make sure your doctor knows if you are:

- 79 • allergic to any medicines, foods, or dyes;
- 80 • taking any other weight-loss medication;
- 81 • taking cyclosporine;
- 82 • taking thyroid medicine;
- 83 • taking any other medicines (including those not prescribed by your doctor);
- 84 • taking any dietary supplements, including herbal products;
- 85 • planning to become pregnant; or
- 86 • anorexic or bulimic.

87 This information will help you and your physician decide if the expected advantages of  
88 XENICAL are greater than any possible disadvantages.

89 **How should I take XENICAL?**

90 The recommended dose is one 120 mg capsule by mouth with liquid at each main meal  
91 that contains fat. You can take XENICAL in conjunction with a mildly reduced-calorie  
92 diet up to 3 times a day. Each time you take XENICAL, your meal should contain no  
93 more than about 30% of calories from fat. Take XENICAL during meals or up to one  
94 hour after a meal. If you occasionally miss a meal or have a meal without fat, you can  
95 omit your dose of XENICAL. Doses greater than 120 mg three times a day have not been  
96 shown to provide an additional weight loss benefit.

97 You should use XENICAL together with a nutritionally balanced, mildly reduced-calorie  
98 diet that contains no more than about 30% of calories from fat. You should evenly divide  
99 your daily intake of fat, carbohydrates, and protein over 3 main meals.

100 You should try to follow a healthy eating plan such as the one developed by the  
101 American Heart Association. Following this eating plan will help you lose weight while  
102 decreasing some of the possible gastrointestinal effects you may experience while taking  
103 XENICAL.

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

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105 **Should I take a multivitamin with XENICAL?**

106 XENICAL interferes with your body's absorption of some fat-soluble vitamins.  
107 Therefore, when you use XENICAL, it is highly recommended that you take a daily  
108 multivitamin supplement containing vitamins D, E, K, and beta-carotene. Take your  
109 multivitamin once a day at least 2 hours before or after taking XENICAL, such as at  
110 bedtime.

111 **Can I take XENICAL while taking other medications?**

112 Be sure to discuss with your doctor all medications (including herbal products) you are  
113 currently taking, including medicines you can get without a prescription (over-the-  
114 counter), to determine if XENICAL can be taken in addition to these medications. If you  
115 are taking cyclosporine, XENICAL and cyclosporine should be taken at least 2 hours  
116 apart. If your cyclosporine levels are being measured, more frequent monitoring may be  
117 necessary. If you are taking levothyroxine, XENICAL and levothyroxine should be taken  
118 at least 4 hours apart.

119 **How long should I use XENICAL?**

120 The use of XENICAL for more than 4 years has not been studied. You and your doctor  
121 should discuss how long you should use XENICAL.

122 **What are the most common side effects of XENICAL?**

123 Because XENICAL works by blocking the absorption of dietary fat, it is likely that you  
124 will experience some changes in bowel habits. These generally occur during the first  
125 weeks of treatment; however, they may continue throughout your use of XENICAL.  
126 These changes may include oily spotting, gas with discharge, urgent need to go to the  
127 bathroom, oily or fatty stools, an oily discharge, increased number of bowel movements,  
128 and inability to control bowel movements. Due to the presence of undigested fat, the oil  
129 seen in a bowel movement may be clear or have a coloration such as orange or brown.

130 These bowel changes are a natural effect of blocking the fat from being absorbed and  
131 indicate that XENICAL is working. They generally occur early in treatment, particularly  
132 after meals containing higher amounts of fat than are recommended. These symptoms are  
133 often temporary and may lessen or disappear as you continue treatment and keep to your  
134 recommended diet of meals containing no more than about 30% fat. However, these side  
135 effects may occur in some individuals over a period of 6 months or longer.

136 In obese adolescent patients treated with XENICAL, the side effects reported were  
137 similar to those observed in adults.

138 **If you are concerned about these or any other side effects you experience while**  
139 **taking XENICAL, talk to your doctor or pharmacist.**

140 **What lifestyle changes should I consider when taking XENICAL?**

141 **You must use XENICAL with a recommended mildly reduced-calorie diet.** You  
142 should also follow a program of regular physical activity, such as walking. **However,**  
143 **before you undertake any activity or exercise program, be sure to speak with your**  
144 **doctor or health care professional.**

145 **How can I reduce dietary fat?**

146 To help you get started on reducing the fat in your diet to around 30%, read the labels on  
147 all the foods you buy. You should avoid foods that contain more than 30% fat while you  
148 are taking XENICAL.

- 149 • When eating meat, poultry or fish, limit your portion to 2 or 3 ounces (roughly the  
150 size of a deck of cards). Choose lean cuts of meat and remove the skin from poultry.  
151 Fill up your meal plate by including more grains, fruits, and vegetables.
- 152 • Replace whole-milk products with nonfat or 1% milk and nonfat, reduced-fat, or low-  
153 fat dairy items.
- 154 • Cook with less fat. Use vegetable oil spray when cooking. Salad dressings, many  
155 baked items, and prepackaged, processed, and fast foods are usually high in fat. Use  
156 the low- or non-fat versions and/or cut back on serving sizes.
- 157 • When dining out, ask how foods are prepared and request that they be prepared with  
158 little or no added fat.

159 **Please visit [www.xenical.com](http://www.xenical.com) to help you succeed with your weight loss goals.**

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