

ALLI- orlistat capsule
Aphena Pharma Solutions - Tennessee, LLC

Drug Facts

Active ingredient (in each sealed capsule)

Orlistat 60 mg

Purpose

Weight loss aid

Use

- for weight loss in overweight adults, 18 years and older, when used along with a reduced-calorie and low-fat diet

Warnings

Organ transplant alert:

- do not use if you have had an organ transplant. Orlistat interferes with the medicines used to prevent transplant rejection.

Allergy alert:

- do not use if you are allergic to any of the ingredients in orlistat capsules

Do not use

- **if you are taking cyclosporine**
- if you have been diagnosed with problems absorbing food
- if you are not overweight

Ask a doctor before use if you have ever had

- gallbladder problems
- kidney stones
- pancreatitis

Ask a doctor or pharmacist before use if you are

- taking any of the following prescription medications. Some prescription doses may need to be adjusted, or some medications may not work as well when used with orlistat.
- anticoagulants (blood thinning medicine)
- amiodarone (heart medicine)
- diabetes medicine
- thyroid disease medicine
- seizure medicine

- antiretrovirals (HIV medicine)
- taking any other weight loss products

When using this product

- **take a multivitamin once a day, at bedtime.** Orlistat can reduce the absorption of some vitamins.
- follow a well-balanced, reduced-calorie, low-fat diet. Try starting this diet before taking orlistat.
- orlistat works by preventing the absorption of some of the fat you eat. The fat passes out of your body, so you may have bowel changes. You may get:
 - gas with oily spotting
 - loose stools
 - more frequent stools that may be hard to control
- eating a low-fat diet lowers the chance of having these bowel changes
- for every 5 pounds you lose from diet alone, orlistat can help you lose 2-3 pounds more. In studies, most people lost 5-10 pounds over 6 months.

Stop use and ask a doctor if

- you develop itching, yellow eyes or skin, dark urine or loss of appetite. There have been rare reports of liver injury in people taking orlistat.
- severe or continuous abdominal pain occurs. This may be a sign of a serious medical condition.
- you are taking medicine for seizures and your seizures happen more often or get worse

If pregnant or breast-feeding, do not use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- read the enclosed brochure for other important information
 - diet and exercise are the starting points for any weight loss program. Try these first before adding orlistat. Check with your doctor before starting any exercise program.
 - to see if orlistat capsules are right for you, find your height on the chart to the right. You may consider starting a weight loss program with orlistat if your weight is the same or more than the weight shown for your height.
 - **for overweight adults 18 years and older:**
 - take 1 capsule with each meal containing fat
 - do not take more than 3 capsules daily
 - use with a reduced-calorie, low-fat diet and exercise program until you reach your weight loss goal. Most weight loss occurs in the first 6 months.
 - if you stop taking orlistat, continue with your diet and exercise program
 - if you start to regain weight after you stop taking orlistat, you may need to start taking orlistat again along with your diet and exercise program
 - **take a multivitamin once a day, at bedtime, when using orlistat**
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	Ht. / Wt.
4'10"	129 lbs.
4'11"	133 lbs.
5'0"	138 lbs.
5'1"	143 lbs.
5'2"	147 lbs.
5'3"	152 lbs.
5'4"	157 lbs.
5'5"	162 lbs.
5'6"	167 lbs.
5'7"	172 lbs.
5'8"	177 lbs.
5'9"	182 lbs.
5'10"	188 lbs.
5'11"	193 lbs.
6'0"	199 lbs.
6'1"	204 lbs.
6'2"	210 lbs.
6'3"	216 lbs.
6'4"	221 lbs.
6'5"	227 lbs.

Other information

- store at 20 - 25 °C (68 - 77 °F)
- protect drug from excessive light, humidity and temperatures over 30 °C (86 °F)

Inactive ingredients

FD&C Blue No. 2, edible ink, gelatin, iron oxide, microcrystalline cellulose, povidone, sodium lauryl sulfate, sodium starch glycolate, talc, titanium dioxide

Questions or comments?

call toll-free **1-800-671-2554**

Additional information

The Starter Pack includes:

- Read Me First brochure
- Up to 20 day supply (60 capsules)

For more information, visit www.myalli.com

TAMPER- EVIDENT features for your protection. The package has a security seal on both ends of the carton printed with the GSK logo. The bottle of capsules has a foil seal under the cap imprinted with the words "sealed for your protection". Each individual capsule is sealed with a dark blue band

around the center of the capsule. DO NOT USE THIS PRODUCT IF ANY OF THESE TAMPER-EVIDENT FEATURES ARE MISSING, TORN OR BROKEN.

For more information and to learn more about **alli**, visit us at www.my.alli.com.

- 1-800-671-2554

Distributed by:

Haleon, Warren, NJ 07059

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Made in India

REPACKAGING INFORMATION

Please reference the HOW SUPPLIED section listed above for a description of drug product's characteristics. This drug product has been received by Aphenia Pharma Solutions - Tennessee, LLC in a manufacturer or distributor packaged configuration and repackaged in full compliance with all applicable cGMP regulations. The package configurations available from Aphenia are listed below:

60mg

NDC 71610-805-34, Bottles of 2280 Capsules

Store between 20°-25°C (68°-77°F). See USP Controlled Room Temperature. Dispense in a tight light-resistant container as defined by USP. Keep this and all drugs out of the reach of children.

Repackaged by:



Cookeville, TN 38506

20240327JK

PRINCIPAL DISPLAY PANEL - 60mg

NDC 71610-805 - Orlistat (Alli) 60mg Capsules - Rx Only

Orlistat (Alli)

2280 Capsules

60mg

2280 Capsules






NDC# 71610-805-34

Store between 20-25 degrees C (68-77 degrees F).
See USP Controlled Room Temperature.
Dispense in a light light-resistant container
as defined by USP.
Keep this and all drugs out of the reach of children

MFG BY: GSK Consumer Healthcare
Warren, NJ
RPKG BY: Aphenix Pharma, Cookeville, TN 38506

Orlistat (Alli)
60mg
71610-805-34

MFG LOT:
GTIN: 10371610805345
S/N: P018197065
BATCH: 3
EXP:

ALLI
orlistat capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71610-805(NDC:0135-0461)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ORLISTAT (UNII: 95M8R751W8) (ORLISTAT - UNII:95M8R751W8)	ORLISTAT	60 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
FERROUS OXIDE (UNII: G7036X8B5H)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	turquoise (capsule) , blue (dark blue band)	Score	no score
Shape	CAPSULE	Size	15mm
Flavor		Imprint Code	Orlistat;60
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:71610-805-34	2280 in 1 BOTTLE; Type 0: Not a Combination Product	03/22/2024	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
NDA	NDA021887		02/07/2007	

Labeler - Aphenia Pharma Solutions - Tennessee, LLC (128385585)

Establishment				
Name	Address	ID/FEI	Business Operations	
Aphenia Pharma Solutions - Tennessee, LLC		128385585	repack(71610-805)	

Revised: 3/2024

Aphenia Pharma Solutions - Tennessee, LLC