

Product name: alli Pharmaceuticals requiring guidance 
<Visceral fat reduction drug>
alli is a trademark of the Haleon Group

alli is a medicine that contains orlistat as the main ingredient and reduces visceral (abdominal) fat. alli works by inhibiting the absorption of fat in the diet.

## **Important Dosage Precautions**

In order to reduce visceral (abdominal) fat by taking this medicine, it is also important to improve your lifestyle (diet and exercise).



## **Precautions for Use**



## **Things You Must Not Do**

(Failure to adhere to this may worsen current symptoms or increase the likelihood of side effects)

#### The following individuals should not take this medicine

- (1) Persons who have had allergic symptoms as a result of taking alli or any component of alli.
- (2) Persons under 18 years of age.
- (3) Persons taking the following medicines: Ciclosporin (immunosuppressant), anti-HIV drugs (AIDS drugs), anticoagulants such as warfarin
- (4) Persons who have received any of the following diagnoses:
  Chronic malabsorption syndrome (failure to absorb nutrients from the diet), cholestasis, obesity due to disease or medication (secondary obesity)
- (5) Persons who are pregnant or who think they may be pregnant.

- (6) Persons who are breastfeeding.
- (7) Persons with a BMI of 35 or more and persons with a BMI of 25 or more but less than 35 who are diagnosed with any of the following:
  - Glucose intolerance (type 2 diabetes, glucose intolerance, etc.)
  - Dyslipidemia Hypertension Hyperuricemia, gout Coronary artery disease: myocardial infarction, angina ● Cerebral infarction: cerebral thrombosis, transient ischemic attack (TIA) ● Non-alcoholic fatty liver disease (NAFLD)
  - Menstrual abnormalities, infertility Obstructive sleep apnea syndrome (OSAS) or obesity hypoventilation syndrome • Motor disorders: osteoarthritis (knee, hip) osteospondylosis, osteoarthritis of hands and fingers
  - Obesity-related kidney disease



### Things To Consult On



- (1) Persons who are currently being treated by a doctor.
- Persons who have had allergic symptoms due to medication in the past.
- (3) Persons who have received any of the following diagnoses: Pancreatitis, gall bladder disorders (e.g. gallstones), kidney disease
- (4) Persons who are taking the following medicines: (Taking alli with other medication may affect the effectiveness of the medication you are currently taking.) Amiodarone (for the heart), levothyroxine (for thyroidism), antiepileptics, antidepressants, antipsychotics (including lithium), benzodiazepines (anxiolytics, sleeping pills), oral contraceptives
- (5) Persons who have been indicated to need re-examination or close examination in a medical checkup.
- If any of the following symptoms occur after taking alli, stop taking alli immediately and consult a physician or pharmacist with these instructions

Relevant Area	Symptoms	
Skin	Rashes, redness, itching, dryness, blisters, abscesses	
Digestive system	Nausea/vomiting, loss of appetite, heartburn, abdominal pain, lethargy, severe abdominal pain, bloody stools	
Neuropsychiatric system	Anxiety	
Urology	Difficulty urinating	
Other	Feeling sluggish	

In rare cases, serious side effects listed on the right may occur. In such cases, see a doctor immediately.

	Symptom Name	Symptoms	
		Itching, hives, hoarse voice, sneezing, itchy throat, breathlessness, palpitations, and confusion may occur immediately after taking alli.	
ı	Liver dysfunction	dysfunction Fever, itching, rashes, jaundice (yellowing of the skin and whites of the eyes), brown urine, general sluggishness, loss of appetite, etc.	
	Kidney stones	Severe abdominal pain may occur when stones move through the ureter, and may be accompanied by nausea and vomiting. Hematuria may be seen.	

3 The following symptoms may appear after taking alli. If such symptoms persist or intensify, stop taking alli and consult a physician or pharmacist with these instructions

Stomach pain, abdominal pain, soft stool, diarrhea, rapid bowel movements, increased or decreased frequency of bowel movements, farting, abdominal distention, abdominal discomfort, farting with stool or oil, leakage of stool or oil, fatty stools (stool with mixed fat or oil layer), decreased fat-soluble vitamins (A, D, E, K) with the following symptoms:

	Fat-soluble vitamins	Symptoms associated with decreased fat-soluble vitamins	
	Vitamin A	Eye discomfort (e.g., poor night vision, dry eyes), skin discomfort (e.g., hardening or cracking of the skin), repeated onset of infection, fever, rashes, redness	
	Vitamin D Pain in the lower back, joints or bones, fractures, muscle weakness, mu		
Vitamin E Anemia (unsteadiness, shortness of breath, palpitations, etc.), neurological symptoms such as numbness and paresthesia			
	Vitamin K	Blue bruising, nosebleeds, abdominal discomfort, persistent black stool, bloody stool, weakness, susceptibility to fatigue, dizziness, increased menstrual bleeding. hematuria, etc.	

If you have taken alli for more than 3 months with no results, consult with a pharmacist to determine whether you need to continue taking alli. If you have taken alli for more than 6 months with no results, stop taking alli and consult your doctor or pharmacist with this instruction manual.

### **Other Precautions**

alli decreases the absorption of fat contained in food and drink into the body. Therefore, oily leakage, flatulence accompanied by stool or oil, and fatty stools may occur.

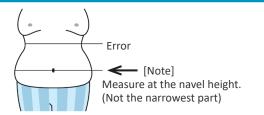
The higher the fat content of your diet, the more likely there will be oily leakage, flatulence accompanied by stool or oil, and fatty stools.

# **Efficacy**

Reduction of visceral (abdominal) fat in patients with a thicker abdomen<sup>(Note)</sup>

(Limited to cases where efforts are being made to improve lifestyle habits)

Note: Waist circumference (navel height): At least 85 cm for men and 90 cm for women  $\,$ 



## Usage/Dosage

Take the following dosages with room-temperature or lukewarm water during or within 1 hour after meals.

Age	Single dose	Number of doses
Adults (18 years and older)	1 capsule 🔗	3 times a day
Under 18 years old	Do not take this m	edicine

#### [Note]

Strictly follow the specified dosage and administration.

However, please refrain from taking this medicine in the following cases.

If you have not eaten, or if you have eaten a meal with negligible fat content

# The first time you take this medicine

(1) Peel off the bottle cap seal and discard it.



(2) Remove and discard the filling. (This filling is intended to prevent damage to capsules during transport. Inserting this in and out of the bottle may cause foreign matter contamination.)

### Component

Orlistat 60 mg per capsule

Additives: cellulose, sodium starch glycolate, sodium lauryl sulfate, povidone, talc, gelatin, polysorbate 80, blue #2, titanium dioxide

## **Precautions for Storage and Handling**

- (1) Store in a cool, dry place away from direct sunlight.
- (2) Keep out of reach of children.
- (3) Do not replace the medicine into a different container. (This may result in misuse or a change in quality)
- (4) Do not take the product after the expiration date.



#### (Disclaimer on Multilingual OTC Product Information)

- •This product is a pharmaceutical product approved under a Japanese law, the Law for Ensuring the Quality, Efficacy and Safety of Drugs and Medical Devices, with a view to its sale and use in Japan.
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