

# Important Drug Safety Notice

## TO ALL PARTICIPATING PHARMACIES

**Circular Letter MC26-014-CG**

**June 15, 2026**

FDA announced that, has approved changes to the **Drugs Facts Label** of the over-the-counter (OTC) weight loss drug, alli (orlistat) 60 mg capsules, to warn of risks of acute kidney injury, which is a rare side effect of the medication. The labeling now advises consumers to ask a health care provider before using alli if they have ever had kidney disease or kidney stones. The labeling changes also tell consumers to stop using alli and ask a doctor if they develop symptoms of kidney injury or kidney stones, such as back or groin pain, painful urination, blood in the urine, feet and leg swelling, or less frequent urination.

The risk of renal (kidney) injury is now described consistently across the labeling for all FDA-approved orlistat products, including those available OTC and those available in a higher strength by prescription.

## RECOMMENDATIONS

### 1. Consumers

- a. Consumers should read the **Drugs Facts Label** carefully before starting alli. It is important for consumers to read the labeling of all OTC medications because they may not have seen a health care provider before deciding to take the medication.
- b. Consumers should be aware there have been rare reports of the following side effects in people taking alli:
  - i. acute kidney injury (kidneys suddenly cannot filter waste products from the blood and harmful levels of waste may build up). Mild cases may be reversible, but untreated severe cases can be fatal.
  - ii. hyperoxaluria (high urinary levels of the waste product oxalate, a compound made by the liver and ingested through the diet)
  - iii. calcium oxalate nephrolithiasis (kidney stones that form when oxalate combines with calcium in the urinary tract)
  - iv. oxalate nephropathy (calcium oxalate crystals form inside the kidneys and interfere with normal kidney function)
- c. If consumers ever had kidney disease or kidney stones, they should ask a health care provider before taking alli.

- d. If consumers experience symptoms of acute kidney injury or kidney stones, they should stop taking alli and consult a health care provider for further guidance. Symptoms may include:
  - i. back or groin pain
  - ii. painful urination
  - iii. blood in the urine
  - iv. feet and leg swelling
  - v. less frequent urination
- e. If consumers experience side effects or do not respond well to alli, they should talk to a health care provider to consider next steps, including whether other treatment options might be right for them.

**2. Health Care Professionals**

- a. Health care professionals who counsel patients about weight loss should inform them about the rare reports of acute kidney injury, hyperoxaluria, calcium oxalate nephrolithiasis, or oxalate nephropathy associated with orlistat products.
  - b. If a patient taking alli presents with signs of acute kidney injury or nephrolithiasis, providers should advise them to stop the drug and proceed with appropriate evaluation and management.
3. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.
4. Expect patients to visit your pharmacy asking for information on this safety issue and prepare your pharmacy staff on how to handle the situation.

**Cordially,**

**MC-Rx Pharmacy Services Department**

## **FDA Approves Labeling Changes for Over-the-Counter (OTC) Weight Loss Drug alli (Orlistat) to Warn of Risk of Kidney Stones and Kidney Injury**

**AUDIENCE:** Consumer, Patient, Health Care Provider, Pharmacy, Gastroenterology, Nephrology, Endocrinology

**ISSUE:** The FDA has approved changes to the **Drugs Facts Label** of the over-the-counter (OTC) weight loss drug, alli (orlistat) 60 mg capsules, to warn of risks of acute kidney injury, which is a rare side effect of the medication. The labeling now advises consumers to ask a health care provider before using alli if they have ever had kidney disease or kidney stones. The labeling changes also tell consumers to stop using alli and ask a doctor if they develop symptoms of kidney injury or kidney stones, such as back or groin pain, painful urination, blood in the urine, feet and leg swelling, or less frequent urination.

The risk of renal (kidney) injury is now described consistently across the labeling for all FDA-approved orlistat products, including those available OTC and those available in a higher strength by prescription.

**BACKGROUND:** alli (orlistat) 60 mg capsules are approved for nonprescription use for weight loss in overweight adults 18 years and older, when used along with a reduced-calorie and low-fat diet. alli is the only FDA-approved OTC (nonprescription) weight loss aid. A higher-strength orlistat product, Xenical (orlistat) 120 mg capsules, is available by prescription. Xenical is indicated for obesity management, including weight loss and weight maintenance, when used in conjunction with a reduced-calorie diet and to reduce the risk for weight regain after prior weight loss.

Orlistat is a lipase inhibitor that works by binding to enzymes that break down fats. As a result, people absorb less dietary fat from the digestive tract.

### **RECOMMENDATIONS:**

#### **Consumers**

- Consumers should read the **Drugs Facts Label** carefully before starting alli. It is important for consumers to read the labeling of all OTC medications because they may not have seen a health care provider before deciding to take the medication.
- Consumers should be aware there have been rare reports of the following side effects in people taking alli:

- acute kidney injury (kidneys suddenly cannot filter waste products from the blood and harmful levels of waste may build up). Mild cases may be reversible, but untreated severe cases can be fatal.
  - hyperoxaluria (high urinary levels of the waste product oxalate, a compound made by the liver and ingested through the diet)
  - calcium oxalate nephrolithiasis (kidney stones that form when oxalate combines with calcium in the urinary tract)
  - oxalate nephropathy (calcium oxalate crystals form inside the kidneys and interfere with normal kidney function)
- If consumers ever had kidney disease or kidney stones, they should ask a health care provider before taking alli.
  - If consumers experience symptoms of acute kidney injury or kidney stones, they should stop taking alli and consult a health care provider for further guidance. Symptoms may include:
    - back or groin pain
    - painful urination
    - blood in the urine
    - feet and leg swelling
    - less frequent urination
  - If consumers experience side effects or do not respond well to alli, they should talk to a health care provider to consider next steps, including whether other treatment options might be right for them.

### **Health Care Professionals**

- Health care professionals who counsel patients about weight loss should inform them about the rare reports of acute kidney injury, hyperoxaluria, calcium oxalate nephrolithiasis, or oxalate nephropathy associated with orlistat products.
- If a patient taking alli presents with signs of acute kidney injury or nephrolithiasis, providers should advise them to stop the drug and proceed with appropriate evaluation and management.