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(IN REPLY PLEASE QUOTE THIS FILE REF.)

11 Jun 2026

Dear Healthcare Professionals,

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

Your attention is drawn to the following FDA's announcement.

What is FDA Doing?

The Food and Drug Administration (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 healthcare 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.

What Is alli?

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.

What Should Consumers Do?

- 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 healthcare 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 healthcare provider before taking alli.
- If consumers experience symptoms of acute kidney injury or kidney stones, they should stop taking alli and consult a healthcare 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 healthcare provider to consider next steps, including whether other treatment options might be right for them.

What Should Healthcare Providers Do?

Healthcare providers 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.

What Did FDA Find?

FDA received periodic safety reports of acute kidney injury associated with alli, which prompted a revaluation of this safety signal in the nonprescription product. Specifically, FDA searched the FDA

Adverse Event Monitoring System (AEMS) and the medical literature to identify cases of acute kidney injury, oxalate nephropathy, hyperoxaluria, and/or calcium oxalate kidney stones that occurred following use of alli. Search dates were from alli's approval date on February 9, 2007, through December 31, 2023.

We identified 12 cases of kidney complications associated with alli use, including nine from AEMS and three from the literature. The median patient age was 61 years (range 36-76 years), and there were slightly more females (7) than males (5). Among the eight patients who reported alli use prior to kidney injury, the median exposure time was 2.5 months (range 0.7-17 months). The types of kidney complications varied among the 12 cases: eight reported acute kidney injury, two reported acute kidney injury with oxalate nephropathy, and two had hyperoxaluria with calcium oxalate kidney stones. The severity of these cases was substantial, with eight patients requiring hospitalization and five requiring dialysis. Seven patients experienced improvement in their conditions, one had not improved at the time the report was made, and four reports did not describe the outcomes. Dosing information was available for four patients, all of whom reported taking either 60 mg or 120 mg of orlistat three times daily.

Our data analysis also suggests that orlistat-associated oxalate nephropathy and kidney injury may not be dose-dependent, as the difference in dietary fat absorption inhibition between the 120 mg (Xenical) and 60 mg (alli) doses is 5%, indicating the risk exists at both prescription and nonprescription doses.

Based on these postmarketing cases demonstrating evidence of kidney injury associated with oxalate crystals in individuals using alli and biological plausibility — as well as findings that the risks may not be dose-dependent — the risk of kidney injury was added to Drug Facts Label for alli, aligning labeling for all FDA-approved orlistat products.

There are limitations to the information available to FDA. The actual number of cases involving kidney problems after alli use may be higher, as consumers and healthcare professionals do not always report side effects to FDA. Many reports were missing information, including clinical details such as kidney stone composition and past medical history. Several people had other possible reasons for their kidney diagnoses besides taking alli, including obesity, diabetes, high blood pressure, and history of kidney disease or kidney stones. These conditions could also have increased the risk of kidney problems associated with the use of alli.

Please refer to the following website in FDA for details:
https://www.fda.gov/drugs/drug-safety-communications/fda-approves-labeling-changes-over-counter-otc-weight-loss-drug-alli-orlistat-warn-risk-kidney

In Hong Kong, there are 12 registered pharmaceutical products containing orlistat, of which 2 products containing orlistat 60mg are pharmacy-only medicines and 10 products containing orlistat 120mg are prescription-only medicines. So far, the Department of Health (DH) has received 4 cases of

adverse drug reaction reports with regard to orlistat, but these cases were not related to kidney stones or kidney injury.

Related news on the risk of urinary crystallization associated with the use of orlistat was previously issued by China State Food and Drug Administration (current National Medical Products Administration), and was posted on the Drug Office website on 8 May 2012. Letters to inform local healthcare professionals were issued by DH on the same day. In Dec 2012, the Registration Committee of the Pharmacy and Poisons Board of Hong Kong (the Registration Committee) discussed the matter and decided that the sales pack label and/or package insert of registered products containing orlistat 120mg should include safety information about the risk of oxalate nephrolithiasis and oxalate nephropathy with renal failure. In light of the above FDA's announcement, the matter will be further discussed by the Registration Committee.

Please note that this letter serves as a means for the DH to communicate important new safety information about registered pharmaceutical products with healthcare professionals in Hong Kong and is not intended to serve as guidelines or to replace professional clinical judgement. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please report any adverse events caused by drugs to the Clinical Trials and Pharmacovigilance Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "ADR Reporting": http://www.drugoffice.gov.hk/adr.html. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly digest of drug safety news and information issued by Drug Office.

Yours faithfully,

(Clive CHAN)
for Assistant Director (Drug)