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### IN BRIEF

## New Warning for OTC Orlistat (*Alli*)

The FDA now requires a warning about a risk of acute kidney injury in the product label for the 60-mg capsules of the pancreatic and gastric lipase inhibitor orlistat, which are available over the counter as *Alli* for weight loss.<sup>1</sup> The label for the 120-mg capsules, which are available by prescription as *Xenical*,<sup>2</sup> already includes a warning about a risk of oxalate nephrolithiasis and oxalate nephropathy (orlistat increases oxalate absorption).

The new warning was based on 12 postmarketing cases of acute kidney injury, oxalate nephropathy, hyperoxaluria, or calcium oxalate kidney stones associated with use of *Alli* 60-mg capsules; 8 of these cases required hospitalization and 5 required dialysis. According to the FDA, the risk of oxalate nephropathy and kidney injury is likely similar with the 60- and 120-mg doses of orlistat.<sup>1</sup>

Patients who have kidney disease or have had kidney stones should consult their healthcare provider before taking *Alli*. The updated label recommends monitoring for signs of kidney injury or kidney stones and stopping the drug if they occur. ■

1. FDA Drug Safety Communication. FDA approves labeling changes for over-the-counter (OTC) weight loss drug alli (orlistat) to warn of risk of kidney stones and kidney injury. June 10, 2026. Available at: <https://bit.ly/4e8GkGA>. Accessed July 1, 2026.
2. Drugs and devices for weight management. *Med Lett Drugs Ther* 2025; 67:121.

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