

Diet Drug Orlistat Linked to Kidney, Pancreas Injuries

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April 14, 2011 (London, Ontario) — A review of patients taking the diet drug **orlistat** (Xenical/Alli, Roche) in Ontario, Canada over a seven-year period points to a 2% increase in acute kidney injuries within one year of patients starting the drug [1].

The findings were reported by **Dr Matthew Weir** (University of Western Ontario, London) and colleagues in a research letter published April 12, 2011 in the *Archives of Internal Medicine*.

Separately, drug-safety watchdog **Public Citizen** has sent a 31-page [letter](#) to FDA commissioner **Dr Margaret Hamburg** demanding that the agency remove both prescription and over-the-counter orlistat from the market, citing new data obtained from FDA adverse-reaction files, including 47 cases of acute pancreatitis and 73 cases of kidney stones. This is the second time Public Citizen has petitioned the FDA to pull the drug from the market.

Orlistat, which is sold as a prescription drug in Ontario (it is sold both by prescription and over the counter, at a lower dose, in the US), has been linked to "oxalate-induced acute kidney injury" in previous case reports. Back in May 2010, the **FDA** issued a warning about the risks of severe liver injury with orlistat use, based on 13 reports of liver toxicity in which two patients died of liver failure and three required liver transplants.

Two recent reports of renal injuries prompted Ontario investigators to look at the incidence of new reports of acute kidney injuries (acute dialysis or a hospital diagnosis of acute kidney injury) in their province in the year prior to patients filling orlistat prescriptions and in the year after filling them.

Among 953 new orlistat patients identified between January 2002 and March 2008, five patients experienced an acute kidney injury event in the 12 months prior to starting on the diet drug. By contrast, 18 patients experienced an event within 12 months after filling their prescription ($p=0.01$). As a "test of specificity," Weir et al also tracked upper-gastrointestinal bleeding in the same fashion ("since there is no plausible reason why orlistat would be associated with this outcome") and found no differences in rates of upper-GI bleeds before and after orlistat prescription.

Weir and colleagues believe their analysis addresses "an important safety issue," although they cannot prove that the kidney injuries were a direct result of orlistat prescription. Despite several limitations of their analysis, they conclude: "In the appropriate setting, physicians should consider orlistat as a potential cause of acute kidney injury."

Late in the day Thursday, GlaxoSmithKline, which sells over-the-counter orlistat (Alli) in the US, announced that Alli is one of the products it will be dropping in 2011 [2]. A company press release says it will be contacting interested buyers for this product and others, with the aim of divesting it by late 2011.

The authors had no disclosures.

References

1. Weir MA, Beyea MM, Gomes T, et al. Orlistat and acute kidney injury: An analysis of 953 patients. *Arch Intern Med* 2011; 171:703-704. [Abstract](#)
2. GlaxoSmithKline. GlaxoSmithKline announces non-core OTC products to be divested [press release]. April 14, 2011. Available [here](#).

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