

[May 2010: New Safety Information For Xenical And Alli Regarding Cases Of Severe Liver Injury](#)

FDA Had Been Investigating Reports Of Hepatotoxicity Involving Their Active Ingredient, Orlistat, For Past Year

(Posted by Tom Lamb at www.DrugInjuryWatch.com on May 26, 2010; see <http://bit.ly/bEp5kp>)

Xenical and Alli are relatively popular medications used for weight-loss that contain different strengths of the same active ingredient, orlistat. Xenical (orlistat 120 mg) is available by prescription and Alli (orlistat 60 mg) is sold over-the-counter without a prescription.

[In late May 2009 we first reported that the FDA was investigating Xenical and Alli for a possible link with liver damage](#) due to the fact that the agency had received case reports of hepatotoxicity involving orlistat.

[About three months later, we reported that the FDA issued its "Early Communication about an Ongoing Safety Review Orlistat \(marketed as Alli and Xenical\)"](#) on August 24, 2009.

Now, by means of a May 26, 2010 announcement by the agency's the Division of Drug Information (DDI), we have learned that (1) the FDA has approved a revised label for Xenical to include new safety information about cases of severe liver injury, and (2) the FDA also wants a new warning about rare reports of severe liver injury added to the OTC Drug Facts label for Alli.

From the ["FDA Drug Safety Communication: Completed safety review of Xenical/Alli \(orlistat\) and severe liver injury"](#), released on May 26, 2010, we get these details:

This new safety information, originally announced in August 2009, is based on FDA's completed review that identified 13 total reports of severe liver injury with orlistat; 12 foreign reports with Xenical and 1 U.S. report with Alli (see Data Summary).

- One U.S. case with Alli and 12 foreign cases with Xenical reported between April 1999 and August 2009 out of an estimated 40 million people worldwide who have used Xenical or Alli.
- Some patients in the reported cases also used other drugs or had other conditions that may have contributed to the development of severe liver injury.
- Severe liver injury can occur in people not taking drugs and without a distinct cause.

At this time, a cause and effect relationship of severe liver injury with orlistat use has not been established....

In addition, the FDA has posted on its web site ["Questions and Answers: Orlistat and Severe Liver Injury"](#), for patients and providers who want to know more about this most recent development concerning Xenical and Alli.

We will continue to monitor the safety profiles of Xenical and Alli, reporting significant developments here at Drug Injury Watch.

Attorney [Tom Lamb](#) represents people in personal injury and wrongful death cases involving unsafe prescription drugs or medication errors. The above article was posted originally on his blog, **Drug Injury Watch** – with live links and readers' Comments.

<http://www.DrugInjuryWatch.com>