

Safety

Orlistat (marketed as Alli and Xenical): Early Communication about an Ongoing Safety Review

Audience: Endocrinological healthcare professionals, patients

FDA notified healthcare professionals and patients that it is reviewing new safety information regarding reports of liver-related adverse events in patients taking orlistat. Orlistat is marketed in the United States as a prescription product, Xenical, and as an over-the-counter (OTC) product, Alli. Between 1999 and October 2008, 32 reports of serious liver injury, including 6 cases of liver failure, in patients using orlistat were submitted to FDA's Adverse Event Reporting System. The most commonly reported adverse events described in the 32 reports of serious liver injury were jaundice, weakness, and abdominal pain. FDA is reviewing other data on suspected cases of liver injury submitted by the manufacturers of orlistat, analysis of these data is ongoing and no definite association between liver injury and orlistat has been established at this time. FDA is not advising healthcare professionals to change their prescribing practices with orlistat. Consumers currently taking Xenical should continue to take it as prescribed and those using over-the-counter Alli should continue to use the product as directed.

FDA urges both healthcare professionals and consumers to report side effects from the use of orlistat (Alli and Xenical) to FDA's [MedWatch Adverse Event Reporting program](#).

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