

Drugs

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

8/24/2009

FDA 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.

Xenical (orlistat 120mg) was approved as a prescription product by FDA in 1999 for obesity management in conjunction with a reduced caloric diet, and to reduce the risk of regaining weight after prior weight loss. In 2007, Alli (orlistat 60mg) was approved for OTC use for weight loss in overweight adults, 18 years and older, in conjunction with a reduced-calorie and low-fat diet. Currently, orlistat is approved for marketing in approximately 100 countries. In January 2009, a nonprescription version of orlistat was approved for sale in the European Union.

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. Thirty of the 32 reports occurred outside the United States. The most commonly reported adverse events described in the 32 reports of serious liver injury were jaundice (yellowing of the skin or whites of the eyes), weakness, and abdominal pain. Hospitalization was reported in 27 of the 32 cases.

In addition to the 32 reported cases, this issue was discussed at the CDER Drug Safety Oversight Board in April 2009, and FDA is reviewing other data on suspected cases of liver injury submitted by the manufacturers of orlistat. FDA's 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.

Consumers should consult their health care professional if they are experiencing symptoms possibly associated with the use of orlistat and development of liver injury, particularly weakness or fatigue, fever, jaundice or brown urine. Other symptoms may include abdominal pain, nausea, vomiting, light-colored stools, itching, or loss of appetite.

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 using the information at the bottom of the page.

This early communication is in keeping with FDA's commitment to inform the public about its ongoing safety reviews of drugs. FDA will communicate its findings to the public as soon as its review of orlistat is complete.

This information reflects FDA's current analysis of available data concerning these drugs. Posting this information does not mean that FDA has concluded there is a causal relationship between the drug products and the emerging safety issue. Nor does it mean that FDA is advising health care professionals to discontinue prescribing these products. FDA is considering, but has not reached a conclusion about whether this information warrants any regulatory action. FDA intends to update this document when additional information or analyses become available

Related Information

- [Orlistat \(marketed as Alli and Xenical\): Early Communication about an Ongoing Safety Review](#)
FDA is reviewing reports of serious liver injury, including liver failure. Posted 08/24/2009
- [Orlistat \(marketed as Alli and Xenical\) Information](#)

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