Orlistat (marketed as Alli and Xenical): Labeling Change

U.S. Food & Drug Administration

FDA notified healthcare professionals and patients that it has approved a revised label for Xenical to include new safety information about cases of severe liver injury that have been reported rarely with the use of this medication. The agency is also adding a new warning about rare reports of severe liver injury to the OTC Drug Facts label for Alli.

Xenical and Alli are 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. This new safety information, originally announced in August 2009, is based on FDA's completed review of orlistat.

Healthcare professionals should weigh the benefits of weight-loss with the potential risks associated with Xenical and Alli before prescribing or recommending these medications to their patients; patients should stop use of orlistat and contact their healthcare professional if they develop the signs and symptoms of liver injury, including itching, yellow eyes or skin, dark urine, light-colored stools, or loss of appetite.

[05/26/2010 - Drug Safety Communication [1] - FDA]
[05/26/2010 - Questions and Answers: Orlistat and Severe Liver Injury [2] - FDA]

Previous MedWatch alert:
[08/24/2009 - Early Communication About an Ongoing Safety Review [3] - FDA]

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