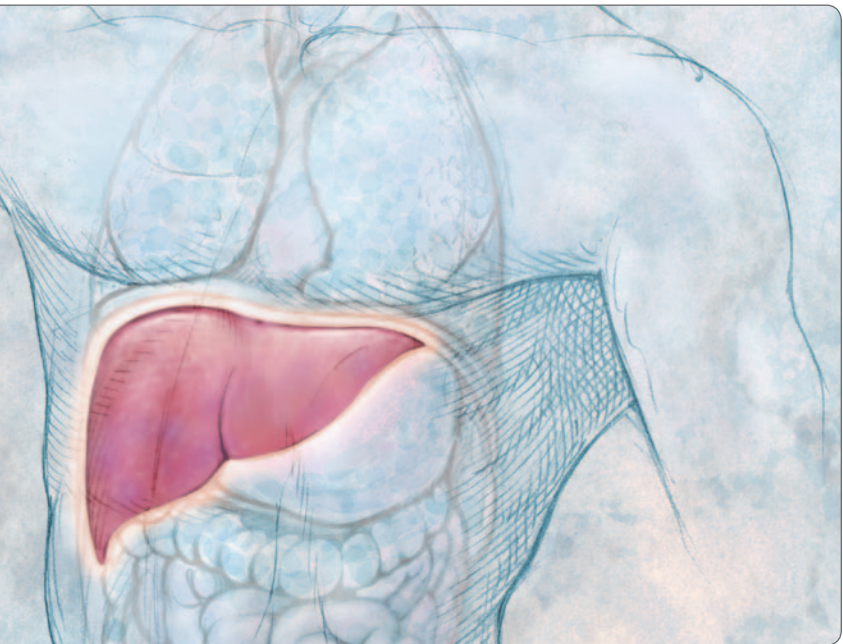


Weight-Loss Drugs and Risk of Liver Failure

Signs of Liver Injury

Itching, yellow eyes or skin, dark urine, loss of appetite, and light-colored stools may be signs of liver injury.



There is a potential, rare occurrence of liver failure in people who take the weight-loss medications Xenical or Alli, according to the Food and Drug Administration (FDA).

The active ingredient in both of these drugs is orlistat. Xenical (orlistat 120 mg) is a prescription product. Alli (orlistat 60 mg) is sold over-the-counter without a prescription.

What Should Consumers Do?

- Contact your health care professional immediately if you experience itching, yellow eyes or skin, dark urine, loss of appetite, or light-colored stools. These may be signs of liver injury.

- Talk to your health care professional if you have any concerns about your treatment with Xenical or Alli.
- Report any side effects with Xenical or Alli to FDA's MedWatch Adverse Event Reporting program either online, by regular mail, by fax, or by phone.
 - Online at www.fda.gov/Safety/MedWatch
 - Regular Mail: Use postage-paid, pre-addressed FDA form 3500 found at www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm
 - Fax: 1-800-FDA-0178
 - Phone: 1-800-332-1088

FDA Actions

FDA has identified and reviewed 12 cases of severe liver injury reported in

people taking Xenical and one case reported with the use of Alli. In some of these cases, other factors or drugs may have contributed to the development of severe liver injury.

A cause-and-effect relationship of severe liver injury with orlistat use has not been established; however, because of the seriousness of this possible side effect, FDA has revised the drug labels for Xenical and Alli to include new safety information about the rare occurrence of severe liver injury. [FDA](#)

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