

# Warning on Hydroxycut Products



This picture shows some of the Hydroxycut products that are being recalled.

FDA / Michael Ermarth

The U.S. Food and Drug Administration (FDA) is warning consumers to immediately stop using Hydroxycut products by Iovate Health Sciences Inc., of Oakville, Ontario and distributed by Iovate Health Sciences USA Inc. of Blasdell, N.Y. Some Hydroxycut products are associated with a number of serious liver injuries. Iovate has agreed to recall Hydroxycut products from the market.

Hydroxycut products are dietary supplements that are marketed for weight loss, as fat burners, as energy-enhancers, as low carb diet aids, and for water loss under the Iovate and Muscletech brand names.

### Serious Health Risks

FDA has received 23 reports of serious health problems ranging from

jaundice and elevated liver enzymes, an indicator of potential liver injury, to liver damage requiring liver transplant. One death due to liver failure has been reported to the FDA.

Liver injury, although rare, was reported by patients at the doses of Hydroxycut recommended on the bottle. Symptoms of liver injury include jaundice (yellowing of the skin or whites of the eyes) and brown urine. Other symptoms include nausea, vomiting, light-colored stools, excessive fatigue, weakness, stomach or abdominal pain, itching, and loss of appetite.

Other health problems reported

include seizures; cardiovascular disorders; and rhabdomyolysis, a type of muscle damage that can lead to other serious health problems such as kidney failure.

FDA urges consumers to stop using Hydroxycut products in order to avoid any undue risk, says Linda Katz, M.D., interim chief medical officer of FDA's Center for Food Safety and Applied Nutrition. "Adverse events are rare, but exist," Katz says. "Consumers should consult a physician or other health care professional if they are experiencing symptoms possibly associated with these products."

Consumers who have the recalled products are advised to stop using them and to return them to the place of purchase. The agency has not yet determined which ingredients, dosages, or other health-related factors may be associated with risks related to these Hydroxycut products. The products contain a variety of ingredients and herbal extracts.

Health care professionals and consumers are encouraged to report serious adverse events (side effects) or product quality problems with the use of these products to FDA's MedWatch Adverse Event Reporting program online, by regular mail, fax or phone.

## Recalled Products

*The list of products being recalled by Iovate currently includes:*

- Hydroxycut Regular Rapid Release Caplets
- Hydroxycut Caffeine-Free Rapid Release Caplets
- Hydroxycut Hardcore Liquid Caplets
- Hydroxycut Max Liquid Caplets
- Hydroxycut Regular Drink Packets
- Hydroxycut Caffeine-Free Drink Packets
- Hydroxycut Hardcore Drink Packets (Ignition Stix)
- Hydroxycut Max Drink Packets
- Hydroxycut Liquid Shots
- Hydroxycut Hardcore RTDs (Ready-to-Drink)
- Hydroxycut Max Aqua Shed
- Hydroxycut 24
- Hydroxycut Carb Control
- Hydroxycut Natural

Although FDA has not received reports of serious liver-related adverse reactions for all Hydroxycut products, Iovate has agreed to recall all the products listed above. Hydroxycut Cleanse and Hoodia products are not affected by the recall.

Online: [www.fda.gov/MedWatch/report.htm](http://www.fda.gov/MedWatch/report.htm)

Regular Mail: Use FDA postage paid form 3500 found at: [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm) and mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787

Fax: 800-FDA-0178

Phone: 800-FDA-1088

FDA continues to investigate the potential relationship between Hydroxycut dietary supplements and liver injury or other potentially serious side effects. [FDA](#)

This article appears on FDA's Consumer Health Information Web page ([www.fda.gov/consumer](http://www.fda.gov/consumer)), which features the latest updates on FDA-regulated products. Sign up for free e-mail subscriptions at [www.fda.gov/consumer/consumerenews.html](http://www.fda.gov/consumer/consumerenews.html).

### For More Information

FDA's Web Page on Hydroxycut Products  
[www.fda.gov/oc/opacom/hottopics/hydroxycut/](http://www.fda.gov/oc/opacom/hottopics/hydroxycut/)

FDA 101: Dietary Supplements  
[www.fda.gov/consumer/updates/supplements080408.html](http://www.fda.gov/consumer/updates/supplements080408.html)