



Safety clinical trial shows possible increased risk of cancer with weight-loss medicine Belviq, Belviq XR (lorcaserin)

FDA continues to evaluate the trial results

1-14-2020 Drug Safety Communication

The U.S. Food and Drug Administration (FDA) is alerting the public that results from a clinical trial assessing safety show a possible increased risk of cancer with the weight management medicine Belviq, Belviq XR (lorcaserin). At this time, the cause of the cancer is uncertain, and we cannot conclude that lorcaserin contributes to the cancer risk. However, we wanted to make the public aware of this potential risk. We are continuing to evaluate the clinical trial results and will communicate our final conclusions and recommendations when we have completed our review.

Health care professionals should consider if the benefits of taking lorcaserin are likely to exceed the potential risks when deciding whether to prescribe or continue patients on lorcaserin.

Patients currently taking lorcaserin should talk to your health care professionals about the potential increased risk of cancer with use of lorcaserin in order to make the best decision about your medical treatment.

Lorcaserin is a prescription medicine approved by FDA in 2012 for use with a reduced-calorie diet and increased physical activity to help weight loss in adults who are obese or are overweight and have weight-related medical problems. Lorcaserin works by increasing feelings of fullness so that less food is eaten. It is available as a tablet (Belviq) and an extended-release tablet (Belviq XR).

When approving lorcaserin, we required the drug manufacturer, Eisai Inc., to conduct a randomized, double-blind, placebo-controlled clinical trial to evaluate the risk of heart-related problems. In this trial, which was conducted in approximately 12,000 participants over 5 years, more patients taking lorcaserin were diagnosed with cancer compared to patients taking placebo, which is an inactive treatment. Our evaluation of this potential signal is ongoing, and at this time it is uncertain if lorcaserin increases the risk of cancer.

To help FDA track safety issues with medicines, we urge health care professionals and patients to report side effects involving lorcaserin or other medicines to the FDA MedWatch program, using the information in the “Contact FDA” box at the bottom of the page.

Related Information

[MedlinePlus: Obesity](#)

[The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective](#)

[Think It Through: Managing the Benefits and Risks of Medicines](#)