

Belviq and Belviq XR Withdrawal Alert

Date of Notice: 02/13/2020

Brief Description of Withdrawal Alert

On February 13, 2020, the FDA has requested the withdrawal of Belviq[®] and Belviq[®] XR because of safety results in a recent clinical trial showing an increased occurrence of cancer. The risks of use outweigh the benefits based on a randomized clinical trial assessing safety.

Affected Products

Drug Name & Strength	NDC	Lot	Expiration Date
Belviq [®] tablets, 10mg	62856-529-60	All lots	All dates
Belviq [®] XR tablets, 20mg	62856-535-30	All lots	All dates

Prescriber Information

Prescribers should stop prescribing and dispensing Belviq[®] and Belviq[®] XR to patients. Alternative weightloss drugs and strategies should be considered and discussed with your patients. The FDA is not recommending any special screening of patients who have taken the drug.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online
- Regular Mail or Fax: <u>Download form</u> or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Member Information

Members should stop taking the drug and talk to your doctor about alternative weight-loss drugs and weight loss programs.

RxAdvance Response

RxAdvance is in the process of notifying members who have recently filled a prescription for this drug.

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