

## FDA announces decision to withdraw Oxandrin® (oxandrolone)

- On June 28, 2023, the <u>FDA announced</u> the final decision to withdraw approval of brand and generic <u>Oxandrin (oxandrolone)</u>. The FDA believes a potential problem associated with oxandrolone tablets is sufficiently serious that the drug products should be removed from the market.
- Oxandrin is indicated as adjunctive therapy to promote weight gain after weight loss following
  extensive surgery, chronic infections, or severe trauma, and in some patients who without definite
  pathophysiologic reasons fail to gain or to maintain normal weight, to offset the protein catabolism
  associated with prolonged administration of corticosteroids, and for the relief of the bone pain
  frequently accompanying osteoporosis.
- As communicated in the product labeling, multiple safety warnings and precautions are associated
  with the use of oxandrolone tablets including peliosis hepatis, sometimes associated with liver
  failure and intra-abdominal hemorrhage; liver cell tumors, sometimes fatal; and blood lipid changes
  that are known to be associated with increased risk of atherosclerosis.
- Per the labeling, additional warnings with using this product include the risks associated with cholestatic hepatitis, hypercalcemia in patients with breast cancer, and increased risk for the development of prostatic hypertrophy and prostatic carcinoma in geriatric patients.
- In March 2019, Gemini, the manufacturer of Oxandrin requested that FDA withdraw approval, stating the product was no longer being marketed. On December 2022, the FDA notified Gemini and other manufacturers that these products should be withdrawn from the market due to safety issues.



At Optum, we help create a healthier world, one insight, one connection, one person at a time. All Optum trademarks and logos are owned by Optum, Inc., in the U.S. and other jurisdictions. All other trademarks are the property of their respective owners. This document contains information that is considered proprietary to Optum Rx and should not be reproduced without the express written consent of Optum Rx. RxNews® is published by the Optum Rx Clinical Services Department.