

Kisqali[®] (ribociclib) – Updated indication

- On July 22, 2024, the <u>FDA approved</u> Novartis' <u>Kisqali (ribociclib)</u>, for treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with fulvestrant as initial endocrine-based therapy or with disease progression following endocrine therapy.
 - Kisqali was previously approved for this indication in combination with fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy *in postmenopausal women or in men*.
- Kisqali is also approved for treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine-based therapy.
- The recommended dose of Kisqali is 600 mg (three 200 mg film-coated tablets) taken orally, once daily for 21 consecutive days followed by 7 days off treatment resulting in a complete cycle of 28 days.
 - When given with Kisqali, the recommended dose of fulvestrant is 500 mg administered on days 1, 15, 29, and once monthly thereafter.
 - Refer to the Kisqali drug label for complete dosing and administration recommendations.



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.