



Mekinist® (trametinib) – New warning

- On February 24, 2017, the FDA approved a new warning to the *Warnings and Precautions* section of the [Mekinist \(trametinib\)](#) drug label regarding colitis and gastrointestinal perforation.
- Mekinist is indicated, as a single agent or in combination with [Tafinlar® \(dabrafenib\)](#), for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test.
 - Mekinist is not indicated for treatment of patients who have received prior BRAF-inhibitor therapy.
- Colitis and gastrointestinal perforation, including fatal outcomes, have been reported in patients taking Mekinist as a single-agent and when administered with dabrafenib.
 - In clinical trials of Mekinist administered as a single agent (n = 329) and Mekinist administered with dabrafenib (n = 559), colitis occurred in 0.6% of patients and gastrointestinal perforation occurred in 0.3% of patients.
 - Patients should be monitored closely for colitis and gastrointestinal perforations.



OptumRx® specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at [optum.com](#).

All Optum® trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews® is published by the OptumRx Clinical Services Department.

©2017 Optum, Inc. All rights reserved.