FARYDAK®
(panobinostat) capsules
10mg/15mg/20mg

FDA-REQUIRED REMS* SAFETY INFORMATION

Boxed Warning: Severe Diarrhea and Cardiac Toxicities With FARYDAK Treatment

Severe Diarrhea

- **Severe diarrhea occurred in 25% of FARYDAK-treated patients**
  - o Severe diarrhea is defined as >7 stools/day, IV fluids or hospitalization
- Diarrhea occurred in 68% of patients treated with FARYDAK compared with 42% in the control arm
- Monitor for symptoms, institute anti-diarrheal treatment, interrupt FARYDAK, and then reduce dose or discontinue FARYDAK. Refer to Factsheet for diarrhea management information available at **www.FARYDAK-REMS.com**

Serious Cardiac Toxicities

- **Severe and fatal cardiac ischemic events, severe arrhythmias, and ECG changes occurred with FARYDAK**
- **Cardiac ischemic events** occurred in 4% of patients treated with FARYDAK compared with 1% of patients in the control arm
- **Arrhythmias** occurred in 12% of patients receiving FARYDAK, compared with 5% of patients in the control arm
- **Do not start** FARYDAK if patient has
  - o Recent myocardial infarction
  - o Unstable angina
  - o QTcF >450 msec
  - o Clinically significant ST-segment or T-wave abnormalities

Indication

FARYDAK® (panobinostat) capsules, a histone deacetylase inhibitor, in combination with bortezomib and dexamethasone, is indicated for the treatment of patients with multiple myeloma who have received **at least 2 prior regimens, including bortezomib and an immunomodulatory agent.**

This indication is approved under accelerated approval based on progression-free survival. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

You are encouraged to report adverse reactions of FARYDAK to Novartis at 1-888-669-6682 and/or the FDA at **www.fda.gov/medwatch** or call 1-800-FDA-1088.

*This journal piece is part of the FDA-required FARYDAK REMS. A REMS (Risk Evaluation and Mitigation Strategy) is a program required by the FDA to manage known or potential serious risks associated with a drug product. Visit **www.FARYDAK-REMS.com** for more information.

For complete safety information, please see the full Prescribing information, including Boxed Warning, available at **www.FARYDAK-REMS.com.**

NOVARTIS ONCOLOGY

Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080

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