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

FDA-REQUIRED REMS* SAFETY INFORMATION

Boxed Warning: Severe Diarrhea and Cardiac Toxicities with FARYDAK Treatment

Dear Healthcare Provider:

The FDA has required this safety notice as part of the FARYDAK® REMS (Risk Evaluation and Mitigation Strategy) to inform you about the following serious risks of FARYDAK:

Severe Diarrhea

- Severe diarrhea occurred in 25% of FARYDAK-treated patients

Cardiac Toxicities

- Severe and fatal cardiac ischemic events, severe arrhythmias, and ECG changes have occurred with FARYDAK

Please see the enclosed REMS Factsheet, a non-promotional factsheet reviewed by the FDA, for more detailed safety information. The factsheet and other important information are also available at **www.FARYDAK-REMS.com**.

Indication

FARYDAK, 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.

*A REMS (**R**isk **E**valuation and **M**itigation **S**trategy) is a program required by the FDA to manage known or potential serious risks associated with a drug product. Please visit **www.FARYDAK-REMS.com** for more information.

For the complete safety profile of FARYDAK, please see the enclosed:

- Prescribing Information
- Medication Guide

Adverse Event Reporting

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.

Sincerely,

Novartis Pharmaceuticals Corporation

NOVARTIS ONCOLOGY

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