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 (Risk Evaluation and Mitigation Strategy) 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
FDA REQUIRED REMS* SAFETY INFORMATION

Boxed Warning: Severe Diarrhea and Cardiac Toxicities with FARYDAK

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 and fatal diarrhea events have occurred in 5% of FARYDAK-treated patients

Cardiac Toxicities

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

Please see the H&L fact sheet, a non-promotional fact sheet reviewed by the FDA, for more detailed safety information. The fact sheet 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.

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For the complete safety profile of FARYDAK, please see the:
- Prescribing Information
- Medication Guide

Adverse Event Reporting

You are encouraged to report adverse reactions of FARYDAK to Novartis at 1 866 506 6602 and/or the FDA at www.fda.gov/medwatch or call 1 800 FDA 1088.

Sincerely,
Novartis Pharmaceutical Corporation

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