

FDA-REQUIRED REMS* SAFETY INFORMATION

Boxed Warning: Severe Diarrhea and Cardiac Toxicities with FARYDAK Treatment

Dear <<insert contact name here>>:

The FDA has required Novartis to distribute this safety notice as part of the FARYDAK[®] REMS (Risk Evaluation and Mitigation Strategy) program. We request that you inform your members 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.

Sincerely,

Novartis Pharmaceuticals Corporation





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Sincerely,
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[Full Prescribing Information](#) | [Medication Guide](#) | [Factsheet](#)



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Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080