Risk Evaluation and Mitigation Strategy (REMS)

What is the 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. FDA has determined that a REMS is necessary to ensure that the benefits of FARYDAK outweigh the risks.

FARYDAK has a Boxed Warning for the following risks:

Severe Diarrhea
- Severe diarrhea occurred in 25% of FARYDAK-treated patients
  - 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 the Fact Sheet for detailed diarrhea management information

Cardiac Toxicities
- Severe and fatal cardiac ischemic events, severe arrhythmias, and ECG changes have 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
  - Recent myocardial infarction
  - Unstable angina
  - QTcF >450 msec
  - Clinically significant ST-segment or T-wave abnormalities

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.
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