FARYDAK® (panobinostat) Capsules
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. The FDA has determined that a REMS is necessary to ensure that the benefits of FARYDAK® (panobinostat) 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 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.