Ponlimsi™
(denosumab-adet)
Injection • 60mg/mL

PONLIMSI REMS

FDA Required REMS Safety Information / Important Safety Update

Dear Healthcare Provider:

The FDA has required this safety update as part of the PONLIMSI REMS (**R**isk **E**valuation and **M**itigation **S**trategy) to inform healthcare providers about the following **serious risk of PONLIMSI (denosumab-adet)**:

Severe Hypocalcemia in Patients with Advanced Kidney Disease

Patients with advanced chronic kidney disease (eGFR < 30 mL/min/1.73 m^2), including dialysis-dependent patients, are at greater risk of severe hypocalcemia following PONLIMSI administration.

- Severe hypocalcemia resulting in hospitalization, life-threatening events and fatal cases have been reported.
- To minimize the risk of hypocalcemia in patients with advanced chronic kidney disease (CKD):
  - Evaluate for the presence of chronic kidney disease-mineral bone disorder (CKD-MBD) with intact parathyroid hormone (iPTH), serum calcium, 25(OH) vitamin D, and 1,25 $(OH)_2$ vitamin D prior to decisions regarding PONLIMSI treatment.
  - Consider assessing bone turnover status (serum markers of bone turnover or bone biopsy) to evaluate the underlying bone disease that may be present.
  - Monitor serum calcium weekly for the first month after PONLIMSI administration and monthly thereafter.
  - Coordinate care with healthcare providers with expertise in CKD-MBD for patients with advanced chronic kidney disease.

Role of the Healthcare Provider

- ✓ **Provide** each patient with a copy of the **Patient Guide**.
- ✓ **Review** information in the **Patient Guide** with each patient, including the serious risk of PONLIMSI and the symptoms of severe hypocalcemia.
- ✓ **Advise** each patient to seek prompt medical attention if they have signs or symptoms of severe hypocalcemia.

This letter does not contain the complete safety profile for PONLIMSI. Please review the enclosed Prescribing Information including BOXED WARNING. All PONLIMSI REMS materials are also available at www.PONLIMSIREMS.com.

Reporting Adverse Events

To report Adverse Reactions with PONLIMSI, please call Teva Pharmaceuticals, Inc. at 1-888-483-8279, option #2, or report the event at FDA MedWatch.

Sincerely,

Teva Pharmaceuticals, Inc.

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