jubbonti®
(denosumab-bbdz) injection
60 mg/mL

Jubbonti REMS

FDA Required REMS Safety Information

June 2025

Important Safety Update

Dear Healthcare Provider:

The FDA has required this safety update as part of the Jubbonti REMS (Risk Evaluation and Mitigation Strategy) to inform healthcare providers about the following **serious risk of Jubbonti**.

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 Jubbonti 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 and 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 Jubbonti 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 Jubbonti 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 Jubbonti 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 Jubbonti. Please review the Prescribing Information enclosed. All Jubbonti REMS materials are also available at www.jubbontirems.com or by contacting your local Sandoz Sales Representative.

Reporting Adverse Events

To report Adverse Reactions with Jubbonti, please call Sandoz Inc. at 1-800-525-8747, or report the event at FDA MedWatch.

Sincerely,

Shaloo Pandhi,
Global Head Patient Safety
Sandoz