Bosaya™
(denosumab-kyqq)

Bosaya™ REMS

FDA Required REMS Safety Information / Important Safety Update

Dear Healthcare Provider:

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

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 BOSAYA 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 BOSAYA 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 BOSAYA 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 BOSAYA 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 BOSAYA. Please review the Prescribing Information enclosed. All BOSAYA REMS materials are also available at www.bosayahcp.com/rems

Reporting Adverse Events

To report Adverse Reactions with BOSAYA, please call Biocon Biologics Inc. at 1-833-986-1468, or report the event at FDA MedWatch.

Sincerely,

Biocon Biologics Inc.

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