

OSVYRTI REMS Letter for Healthcare Provider

FDA Required REMS Safety Information / Important Safety Update

Date: _____

Dear Healthcare Provider:

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

Severe Hypocalcemia in Patients with Advanced Kidney Disease

Patients with advanced chronic kidney disease (eGFR < 30 mL/min/1.73 m²), including dialysis-dependent patients, are at greater risk of severe hypocalcemia following OSVYRTI 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 OSVYRTI 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 OSVYRTI 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 risks of OSVYRTI 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 OSVYRTI. Please review the Prescribing Information enclosed.

All OSVYRTI REMS materials are also available at www.osvyrtihcp.com/risk-evaluation-mitigation-strategy.

Reporting Adverse Events

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088. Healthcare providers should report all suspected adverse events associated with OSVYRTI to the FDA or to Accord BioPharma at 1-866-941-7875.

Sincerely,
Accord BioPharma