

# FDA REQUIRED REMS Safety Information for Prolia<sup>®</sup> (denosumab)

## Serious Risks Associated with Prolia<sup>®</sup>:

### Hypocalcemia and Mineral Metabolism

Hypocalcemia may be exacerbated by the use of Prolia<sup>®</sup>. In patients predisposed to hypocalcemia and disturbances of mineral metabolism, clinical monitoring of calcium and mineral levels is highly recommended.

### Osteonecrosis of the Jaw

Osteonecrosis of the Jaw (ONJ) has been reported in patients receiving Prolia<sup>®</sup>. ONJ, which can occur spontaneously, is generally associated with tooth extraction and/or local infection with delayed healing.

### Atypical Subtrochanteric and Diaphyseal Femoral Fractures

Atypical low-energy or low trauma subtrochanteric and diaphyseal femoral fractures, which may be bilateral, have been reported in patients receiving Prolia<sup>®</sup>. Atypical femoral fractures most commonly occur with minimal or no trauma to the affected area.

### Serious Infections

In a clinical trial, women with postmenopausal osteoporosis treated with Prolia<sup>®</sup> presented with serious infections, such as infections of the abdomen, urinary tract, and ear, as well as endocarditis.

### Dermatologic Reactions

In a clinical trial, women with postmenopausal osteoporosis treated with Prolia<sup>®</sup> presented with generalized epidermal and dermal adverse events at a significantly higher rate compared to the placebo group.

## Role of the Healthcare Provider

- ✓ **Review** information in the Prolia<sup>®</sup> Medication Guide and Patient Counseling Chart with each patient, including the serious risks of Prolia<sup>®</sup> and the symptoms of each risk.
- ✓ **Advise** each patient to seek prompt medical attention if they have signs or symptoms of any of the serious risks.
- ✓ **Provide** each patient a copy of the Medication Guide and Patient Brochure.

## Prolia<sup>®</sup> is Indicated for the:

- Treatment of postmenopausal women with osteoporosis at high risk for fracture
- Treatment to increase bone mass in men with osteoporosis at high risk for fracture
- Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer
- Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer

### Reporting Adverse Events

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088. Healthcare providers should report all suspected adverse events associated with Prolia<sup>®</sup> to the FDA or to Amgen at 1-800-772-6436.

*This journal information piece is part of the FDA-required Prolia<sup>®</sup> REMS. Visit [www.proliahcp.com/risk-evaluation-mitigation-strategy](http://www.proliahcp.com/risk-evaluation-mitigation-strategy) for more information.*

*For complete safety information, see the Prescribing Information available at [www.proliahcp.com/risk-evaluation-mitigation-strategy](http://www.proliahcp.com/risk-evaluation-mitigation-strategy).*

