

# Prolia® (denosumab) Risk Evaluation and Mitigation Strategy

## What is the Prolia® REMS?

A REMS (Risk Evaluation and Mitigation Strategy) is a program required by the Food and Drug Administration to manage known or potential serious risks associated with a drug product.

The purpose of the Prolia® REMS is to inform healthcare providers and patients about the following serious risks of:

- ▶ Hypocalcemia
- ▶ Osteonecrosis of the jaw
- ▶ Atypical femoral fractures
- ▶ Serious infections
- ▶ Dermatologic reactions

The Prolia® REMS program materials are designed to inform healthcare providers and patients about these risks with Prolia®. They include a REMS Letter for Healthcare Providers, Patient Counseling Chart for Healthcare Providers, Patient Brochure, Journal Information Piece, Prescribing Information, and Medication Guide. It is important that you discuss with your patients the information included in the Patient Counseling Chart for Healthcare Providers, the Patient Brochure, and the Medication Guide.

**To learn more about the serious risks of Prolia®, read the [Important Safety Information](#) provided in this link and use the links on the right to access REMS supporting materials.**

## 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® to the FDA or to Amgen at 1-800-772-6436.

### Materials for Healthcare Providers

 [REMS Letter for Healthcare Providers ▶](#)

 [Journal Information Piece ▶](#)

### Patient Counseling Toolkit

 [Patient Counseling Chart for Healthcare Providers ▶](#)

 [Patient Brochure ▶](#)

 [Prescribing Information ▶](#)

 [Medication Guide ▶](#)

### Materials for Patients

 [Patient Brochure ▶](#)

 [Medication Guide ▶](#)



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CHRISTINE P NGUYEN  
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