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 risk of:

- Severe Hypocalcemia in Patients with Advanced Kidney Disease

The Prolia® REMS program materials are designed to inform healthcare providers and patients about this risk with Prolia®. The Prolia® REMS program materials include a REMS Letter for Healthcare Providers and a Patient Guide. It is important that you discuss with each patient the information included in the Patient Guide.

To learn more about the serious risk 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, or call 1-800-FDA-1088. Healthcare providers should report all suspected adverse events associated with Prolia® to the FDA or to Amgen Inc. at 1-800-772-6436.

Materials for Healthcare Providers

REMS Letter for Healthcare Providers

Patient Guide

Prescribing Information

Materials for Patients

Patient Guide

prolia® (denosumab) injection