



Summary of investigation results

Denosumab (genetical recombination)

(drug product with the indication for osteoporosis)

April 20, 2017

Non-proprietary name

Denosumab (genetical recombination) (drug product with the indication for osteoporosis)

Brand name (Marketing authorization holder)

Pralia Subcutaneous Injection Syringe 60 mg (Daiichi-Sankyo Company, Limited)

Indications

Osteoporosis

Summary of revision

- (1) Precaution for “Multiple vertebral fractures after discontinuation of denosumab treatment” should be newly added in the Important Precautions section.
- (2) “Multiple vertebral fractures after discontinuation of denosumab treatment” should be newly added in the Clinically Important Adverse Reactions section.

Background of the revision and investigation results

Off-treatment follow-up results of overseas clinical studies showed a higher incidence of multiple new vertebral fractures in patients who discontinued denosumab compared with those who discontinued placebo. The company core data sheet (CCDS)* has been revised based on the follow-up results. In addition, overseas clinical studies which were conducted before the approval of denosumab showed a temporary increase in bone resorption after discontinuation of denosumab treatment. The time to onset of the multiple new vertebral fractures after discontinuation of denosumab treatment found in the follow-up was not



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inconsistent with the time to onset of the temporary increase in bone resorption. Based on these findings, the opinions of expert advisors, and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan

No case related to multiple vertebral fractures after discontinuation of denosumab treatment has been reported in patients with osteoporosis.

NOTE:

*CCDS is prepared by the marketing authorization holder and covers material relating to safety, indications, dosing, pharmacology, and other information concerning the product.