



*This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.*

# Revision of Precautions

## 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)

### Safety measure

Precautions should be revised in the package insert.

In the Important Precautions section, the following text should be added (underlined parts are revised):

In patients with osteoporosis, multiple vertebral fractures, which may be associated with a temporary increase in bone resorption, may occur after discontinuation of denosumab treatment. If the treatment is discontinued, transitioning to an alternative antiresorptive agent should be considered.

In the Clinically Significant Adverse Reactions subsection of the Adverse Reactions section, the following text should be added (underlined parts are revised):

Multiple vertebral fractures after discontinuation of denosumab treatment: In patients with osteoporosis, multiple vertebral fractures may occur after discontinuation of denosumab treatment.