



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.