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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) (120 mg product)

March 19, 2019

## Non-proprietary name

Denosumab (genetical recombination) (120 mg product)

## Safety measure

Precautions should be revised in the package insert.

The following language should be added to the Clinically Significant Adverse Reactions subsection of the Adverse Reactions section (revised language is underlined):

<u>Hypercalcaemia after discontinuation of denosumab treatment:</u> <u>In patients with bone giant cell tumour, hypercalcaemia may occur after discontinuation of</u> <u>denosumab treatment.</u>

<u>Multiple vertebral fractures after discontinuation of denosumab treatment:</u> <u>Multiple vertebral fractures may occur after discontinuation of denosumab treatment.</u>

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