



*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):

Hypercalcaemia after discontinuation of denosumab treatment:

In patients with bone giant cell tumour, hypercalcaemia may occur after discontinuation of denosumab treatment.

Multiple vertebral fractures after discontinuation of denosumab treatment:

Multiple vertebral fractures may occur after discontinuation of denosumab treatment.