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Translated by
Pharmaceuticals and Medical Devices Agency



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)

July 20, 2021

Therapeutic category

Agents affecting metabolism, n.e.c. (not elsewhere classified)

Non-proprietary name

Denosumab (genetical recombination)

Safety measure

Precautions should be revised in the package insert.

Pharmaceuticals and Medical Devices Agency

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Revision in line with the Instructions for Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0608-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 8, 2017 (New instructions): Revised language is underlined.

Current	Revision
<p>8. IMPORTANT PRECAUTIONS</p> <p>Cases of atypical fracture of subtrochanteric femur <u>and</u> proximal femoral shaft that is associated with no trauma have been reported in patients on long-term treatment with this drug or bisphosphonates. In some of the cases, prodromal pain in the femur, inguinal, or other sites started several weeks to months before complete fracture occurred. If such symptoms are observed following initiation of this drug, X-ray examination, etc. should be performed and appropriate measures should be taken.</p> <p>In addition, bilateral fracture may occur. If unilateral atypical fracture occurs, patients should be carefully monitored by checking symptoms of the other <u>femur</u> and performing an X-ray examination. Characteristic findings noted in X-rays such as a thickened bone lateral cortex have been reported. If such signs are observed, appropriate measures should be taken.</p> <p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>Atypical fracture of subtrochanteric femur <u>and</u> proximal femoral shaft</p>	<p>8. IMPORTANT PRECAUTIONS</p> <p>Cases of atypical fracture of subtrochanteric femur, proximal femoral shaft, <u>proximal ulnar shaft, or other sites</u> that is associated with no trauma <u>or induced by mild external force</u> have been reported in patients on long-term treatment with this drug or bisphosphonates. In some of the cases, prodromal pain in the femur, inguinal, <u>forearm</u>, or other sites started several weeks to months before complete fracture occurred. If such symptoms are observed following initiation of this drug, X-ray examination, etc. should be performed and appropriate measures should be taken. In addition, bilateral fracture may occur. If unilateral atypical fracture occurs, patients should be carefully monitored by checking symptoms of <u>the sites</u> on the other side and performing an X-ray examination. Characteristic findings noted in X-rays such as a thickened bone lateral cortex have been reported. If such signs are observed, appropriate measures should be taken.</p> <p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>Atypical fracture of subtrochanteric femur, proximal femoral shaft, <u>proximal ulnar shaft, or other sites</u></p>

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