

This document is an English-translated version of an attachment of a notification for Revision of PRECAUTIONS issued by the Ministry of Health, Labour and Welfare.

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

Burosumab (genetical recombination)

January 13, 2026

Therapeutic category

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

Non-proprietary name

Burosumab (genetical recombination)

Safety measure

PRECAUTIONS should be revised.

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Revised language is underlined.

Current	Revision
<p>8. IMPORTANT PRECAUTIONS (newly added)</p> <p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p>9.1 Patients with Complications or History of Diseases, etc. Patients with hypercalcaemia Hypercalcaemia may worsen.</p> <p>11. ADVERSE REACTIONS (newly added)</p>	<p>8. IMPORTANT PRECAUTIONS</p> <p><u>Increase in serum calcium or PTH may occur in patients treated with this drug. Serum calcium and PTH levels should be measured prior to and periodically during treatment with this drug.</u></p> <p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p>9.1 Patients with Complications or History of Diseases, etc. Patients with hypercalcaemia <u>or those with risk factors for hypercalcaemia (hyperparathyroidism, immobilisation, dehydration, hypervitaminosis D, renal impairment, etc.)</u> <u>Patients with moderate to severe hypercalcaemia prior to starting treatment with this drug should not receive this drug until hypercalcaemia is adequately treated.</u> Hypercalcaemia may <u>develop or worsen. In particular, severe hypercalcaemia after administration of this drug has been reported in patients with tertiary hyperparathyroidism.</u></p> <p>11. ADVERSE REACTIONS</p> <p><u>11.1 Clinically Significant Adverse Reactions</u></p> <p><u>Hypercalcaemia</u> <u>Attention should be paid to the onset of clinical symptoms considered to be due to hypercalcaemia (irritation, malaise, inappetence, constipation, etc.). When moderate to severe</u></p>

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	<u>hypercalcaemia is detected, treatment with this drug should be discontinued until hypercalcaemia is adequately treated.</u>
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