独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Summary of Investigation Results

Burosumab (genetical recombination)

January 13, 2026

Non-proprietary name

Burosumab (genetical recombination)

Brand name (marketing authorization holder)

Crysvita Subcutaneous Injection 10 mg, Crysvita Subcutaneous Injection 20 mg, Crysvita Subcutaneous Injection 30 mg, Crysvita Subcutaneous Injection 10 mg Syringe, Crysvita Subcutaneous Injection 20 mg Syringe, Crysvita Subcutaneous Injection 30 mg Syringe (Kyowa Kirin Co., Ltd.)

Japanese market launch

Crysvita Subcutaneous Injection: December 2019

Crysvita Subcutaneous Injection Syringe: November 2025

Indications

FGF23-related hypophosphatemic rickets/osteomalacia

Summary of revisions

1. A statement to the effect that serum calcium and PTH levels should be periodically measured should be added to 8. IMPORTANT PRECAUTIONS.
2. “Patients with risk factors for hypercalcaemia (hyperparathyroidism, immobilisation, dehydration, hypervitaminosis D, renal impairment, etc.)" should be added to the 9.1.1 Patients with hypercalcaemia section in the 9.1 Patients with Complications or History of Diseases, etc. section in 9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS.
3. “Hypercalcaemia” should be added to the 11.1 Clinically Significant Adverse Reactions section in 11. ADVERSE REACTIONS.

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Investigation results and background of the revision

Cases involving hypercalcaemia were evaluated. Cases in which a causal relationship between burosumab (genetical recombination) and hypercalcaemia was reasonably possible have been reported. As a result of consultation with expert advisors regarding the causality assessment of the cases and the necessity of revision of PRECAUTIONS, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary.

Reference: Number of cases* and patient mortalities involving hypercalcaemia reported in Japan and overseas

A total of 3 cases have been reported in Japan to date (including 2 cases in which a causal relationship between the drug and the event was reasonably possible).
No patient mortalities have been reported in Japan to date.

One case has been reported overseas to date. (A causal relationship between the drug and the event could not be established for this case.)
No patient mortalities have been reported overseas to date.

*: Among cases collected in the PMDA's safety database for drugs, cases which correspond to MedDRA PT “Hypercalcaemia” and “Blood calcium increased” were retrieved.

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the “Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency” (PMDA Administrative Rule No. 20-8, dated December 25, 2008).