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(IN REPLY PLEASE QUOTE THIS FILE REF.)

26 Aug 2025

Dear Healthcare Professionals,

Important safety information on CRYSVITA (burosumab) and the risk of severe hypercalcemia in patients with tertiary hyperparathyroidism

Your attention is drawn to the following Health Canada's announcement.

Affected products

CRYSVITA (burosumab), solution for subcutaneous injection: 10 mg/mL, 20 mg/mL and 30 mg/mL.

Issue

CRYSVITA (burosumab) may increase the risk of severe hypercalcemia in patients with underlying tertiary hyperparathyroidism and other risk factors, such as prolonged immobilization, dehydration, hypervitaminosis D, or renal impairment.

Audience

Healthcare professionals including pediatric and adult endocrinologists, and other specialists who are experienced in the diagnosis and management of rare metabolic bone diseases and who manage, or are likely to manage X-linked hypophosphatemia and FGF23-related hypophosphatemia in tumor-induced osteomalacia.

Key messages

- CRYSVITA (burosumab) may increase the risk of severe hypercalcemia in patients with underlying tertiary hyperparathyroidism and other risk factors.
- Healthcare professionals are advised that:
  - CRYSVITA should NOT be administered in patients with moderate to severe hypercalcemia until the condition has been adequately managed.
  - Serum calcium and parathyroid hormone levels should be monitored before and during treatment with CRYSVITA.

- The Canadian Product Monograph for CRYSVITA has been updated to include this information.

Background

CRYSVITA is indicated for the treatment of:

- X-linked hypophosphatemia in adult and pediatric patients 6 months of age and older.
- FGF23-related hypophosphatemia in tumor-induced osteomalacia associated with tumors that cannot be curatively resected or localized in adult patients.

Mild to moderate elevation of serum calcium levels have been reported in patients treated with CRYSVITA, including some cases occurring at treatment initiation. In several of these reports, a rise in parathyroid hormone levels after starting CRYSVITA was also noted.

In the post-market setting, severe hypercalcemia has been reported in patients with underlying tertiary hyperparathyroidism in association with other risk factors for hypercalcemia, such as prolonged immobilization, dehydration, hypervitaminosis D, or renal impairment.

CRYSVITA may affect calcium levels through the restoration of phosphate homeostasis. The effect on parathyroid hormone as a result of CRYSVITA inhibition of FGF23 remains unclear.

Information for consumers

CRYSVITA is used to treat X-linked hypophosphatemia (low levels of phosphate in the blood) in adults and children 6 months of age and older. CRYSVITA is also used to treat hypophosphatemia in adults with tumor-induced osteomalacia (soft bones caused by a type of tumor).

CRYSVITA may cause hypercalcemia (high levels of calcium in the blood), especially in patients who already have a condition called tertiary hyperparathyroidism (persistently high levels of parathyroid hormone [a hormone that helps control blood calcium and phosphate levels] in the blood caused by other long-standing conditions) and other risk factors for hypercalcemia, including being immobile for a long time, not drinking enough fluids, taking too much vitamin D, or having kidney problems. CRYSVITA may also be associated with increases in parathyroid hormone.

To reduce these risks, healthcare professionals should check the calcium and parathyroid hormone levels in patients' blood before and during treatment. Mild to moderate hypercalcemia often causes few or no symptoms. When symptoms do occur, they may include constipation, nausea, vomiting, abdominal pain, loss of appetite and excessive urination. Long-term or severe hypercalcemia can result in kidney damage, abnormal heart rhythms and nervous system dysfunction.

Patients should discuss any questions or concerns about this information with their healthcare professional.. Patients should inform their healthcare professional if they are experiencing any side effects while receiving CRYSVITA.

Information for healthcare professionals

Healthcare professionals are advised that:

- CRYSVITA should NOT be administered in patients with moderate to severe hypercalcemia until the condition has been adequately managed.
- Serum calcium and parathyroid hormone levels should be monitored before and during treatment with CRYSVITA.

Action taken by Health Canada

Health Canada, in collaboration with Kyowa Kirin, Inc., has updated the Canadian Product Monograph for CRYSVITA to include this new information.

Please refer to the following website in Health Canada for details:
https://recalls-rappels.canada.ca/en/alert-recall/important-safety-information-crysvita-burosumab-and-risk-severe-hypercalcemia-patients

In Hong Kong, Crysvita Solution For Injection 10 mg/1ml (HK-66641), Crysvita Solution For Injection 20 mg/1ml (HK-66642) and Crysvita Solution For Injection 30 mg/1ml (HK-66643) are pharmaceutical products containing burosumab registered by DKSH Hong Kong Limited. All products are prescription-only medicines. So far, the Department of Health (DH) has not received any case of adverse drug reaction with regard to burosumab. In light of the above Health Canada's announcement, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board of Hong Kong.

Please note that this letter serves as a means for the DH to communicate important new safety information about registered pharmaceutical products with healthcare professionals in Hong Kong and is not intended to serve as guidelines or to replace professional clinical judgement. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please report any adverse events caused by drugs to the Clinical Trials and Pharmacovigilance Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "ADR Reporting": http://www.drugoffice.gov.hk/adr.html. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly digest of drug safety news and information issued by Drug Office.

Yours faithfully,

(Vincent CHIANG)
for Assistant Director (Drug)