

B-11-01, The Ascent,
Paradigm, No. 1, Jalan SS 7/
26A, Kelana Jaya, 47301
Petaling Jaya, Selangor Darul
Ehsan, Malaysia

14 September 2026

Direct Healthcare Professional Communication:

Crysvita 10 mg solution for Injection (MAL22126021ARZ)
Crysvita 20 mg solution for Injection (MAL22126022ARZ)
Crysvita 30 mg solution for Injection (MAL22126023ARZ)

Crysvita (burosumab): Risk of severe hypercalcaemia

Dear Sir / Madam,

DKSH Malaysia Sdn Bhd as the Product Registration Holder (PRH) in Malaysia would like to inform you of important safety information regarding the use of burosumab:

Summary

- **Increases in serum calcium, including severe hypercalcaemia, and/or parathyroid hormone have been reported in patients treated with burosumab.**
- **In particular, severe hypercalcaemia has been reported in subjects with tertiary hyperparathyroidism.**
- **In patients with moderate to severe hypercalcaemia (> 3.0 mmol/L), burosumab should not be administered until hypercalcaemia is adequately treated and resolved.**
- **Monitoring for patients treated with burosumab should include:**
 - **serum calcium before initiation of treatment, 1-2 weeks after initiation and dose adjustments, and during treatment every 6 months (every 3 months for children aged 1-2 years),**
 - **parathyroid hormone every 6 months (every 3 months for children aged 1-2 years).**
- **Factors such as hyperparathyroidism, prolonged immobilisation, dehydration, hypervitaminosis D or renal impairment may increase the risk of hypercalcaemia.**

The communication of this information has been agreed with the National Centre for Adverse Drug Reaction Monitoring, National Pharmaceutical Regulatory Agency (NPRA), Ministry of Health Malaysia.

Indications approved in Malaysia

Crysvita (burosumab) is indicated for the treatment of:

- X-linked hypophosphataemia (XLH), in children and adolescents aged 1 to 17 years with radiographic evidence of bone disease, and in adults.

Further information on the safety concern

Cases of severe hypercalcaemia have been reported in the post-marketing setting in patients treated with burosumab who have tertiary hyperparathyroidism associated with other risk factors for hypercalcaemia.

Initiation of burosumab may affect calcium levels due to restoration of phosphate homeostasis. The effect on parathyroid hormone as a result of burosumab inhibition of FGF23 is, however, unknown.

To prevent occurrence of severe hypercalcaemia in vulnerable patients, the following is recommended:

- Serum calcium and parathyroid hormone levels should be monitored before and during burosumab treatment. Serum calcium should be measured 1-2 weeks after burosumab initiation and in case of dose adjustment. Calcium and parathyroid hormone should be determined every 6 months (every 3 months for children aged 1-2 years).
- Particular attention should be given to patients with underlying tertiary hyperparathyroidism since they are at risk of developing moderate to severe hypercalcaemia. Other risk factors for hypercalcaemia, such as prolonged immobilisation, dehydration, hypervitaminosis D, or renal impairment, must also be considered and adequately managed.
- Hypercalcaemia should be controlled, following local clinical practice guidelines, before burosumab initiation or if identified during treatment.

Status for product information

The product information is being revised to include this new information. Hyperparathyroidism, hypercalcaemia, hypercalciuria, and blood parathyroid hormone increased are being added as possible adverse reactions for burosumab, and recommendations for monitoring are being incorporated.

Call for adverse event reporting

To make a report, contact the National Centre for Adverse Drug Reaction Monitoring, NPRA:

- i) Visit www.npra.gov.my
- ii) Select "Reporting ADR" under Health Professionals
 - a) Choose Online Reporting; or
 - b) Download the manual form and submit the completed form via email to fv@npra.gov.my;
Alternatively, post to:
Pharmacovigilance Section
National Pharmaceutical Regulatory Agency (NPRA)
Lot 36, Jalan Profesor Diraja Ungku Aziz (Jalan Universiti)
46200 Petaling Jaya
Selangor, Malaysia

Adverse drug reactions should also be reported to DKSH Malaysia Sdn Bhd Pharmacovigilance team at:
PharmacovigilanceMY@dksh.com or Adverse.hec@dksh.com

For further medical information on Crysvita (Burosumab), please contact the Responsible Person for Pharmacovigilance (RPPV) in DKSH Malaysia Sdn BHD at:

Email: PharmacovigilanceMY@dksh.com or Adverse.hec@dksh.com.

Phone number: +603 2778 4604

Sincerely,



Digitally signed
by Wendy Low
Date: 2020.09.21
13:46:56 +08'00'

Wendy Low (RPPV),
Executive, Pharmacovigilance

References

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