

# CRYSVITA® (burosumab) dosing factsheet for paediatric patients with X-linked hypophosphataemia (XLH)

CRYSVITA® 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.<sup>1</sup>



## Starting CRYSVITA®

Oral phosphate and active vitamin D analogues (e.g. calcitriol) should be discontinued 1 week prior to initiation of treatment. Vitamin D replacement or supplementation with inactive forms may be started or continued as per local guidelines under monitoring of serum calcium and phosphate. The recommended starting dose in children and adolescents aged 1 to 17 years is 0.8 mg/kg of body weight given every 2 weeks. Doses should be rounded to the nearest 10 mg. The maximum dose is 90 mg.<sup>1</sup>

## Measurement of fasting serum phosphate

After initiation of treatment with burosumab, fasting serum phosphate should be measured every 2 weeks for the first month of treatment, every 4 weeks for the following 2 months and thereafter as appropriate. Fasting serum phosphate should also be measured 4 weeks after any dose adjustment. If fasting serum phosphate is within the reference range for age, the same dose should be maintained.<sup>1</sup>

### Dose increase<sup>1</sup>

If fasting serum phosphate is below the reference range for age, the dose may be increased stepwise by 0.4 mg/kg up to a maximum dose of 2.0 mg/kg (maximum dose of 90 mg). Fasting serum phosphate should be measured 4 weeks after dose adjustment. Burosumab should not be adjusted more frequently than every 4 weeks.

### Dose decrease<sup>1</sup>

If fasting serum phosphate is above the reference range for age, the next dose should be withheld and the fasting serum phosphate reassessed within 4 weeks. The patient must have fasting serum phosphate below the reference range for age to restart burosumab at half of the previous dose, rounding the amount as described above.

### Missed dosing<sup>1</sup>

Treatments may be administered 3 days either side of the scheduled treatment date if needed for practical reasons. If a patient misses a dose, burosumab should be resumed as soon as possible at the prescribed dose.

CRYSVITA® is available as a 10 mg / 20 mg / 30 mg solution for injection.

Each vial contains 10 mg / 20 mg / 30 mg of CRYSVITA® in 1 ml solution.

**The maximum dose is 90 mg irrespective of weight.**



**Burosumab should not be adjusted more frequently than every 4 weeks.<sup>1</sup>**

## SAMPLE STARTING DOSE CALCULATION –PATIENTS 1–17 YEARS

**Patient weight (kg) x Recommended starting dose (0.8 mg/kg)**

Example: 23 kg x 0.8 mg/kg = 18.4 mg (**Round to nearest 10 mg**)  
Starting dose of CRYSVITA® = 20 mg (**The maximum dose is 90 mg**)

**REFERENCE** 1. CRYSVITA® (burosumab) Malaysia Package Insert. September 2022, Version 1

PLEASE REFER TO THE FULL PRESCRIBING INFORMATION BEFORE PRESCRIBING.  
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For X-linked hypophosphataemia (XLH)

## CRYSVITA® Abbreviated Product Information

CRYSVITA® (burosumab) Malaysia Package Insert. September 2022, Version 1

**INDICATIONS AND USAGE:** CRYSVITA® is indicated for the treatment of X-linked hypophosphataemia, in children and adolescents aged 1 to 17 years with radiographic evidence of bone disease, and in adults.

**DOSAGE AND ADMINISTRATION:** Treatment should be initiated by a physician experienced in the management of patients with metabolic bone diseases. Oral phosphate and active vitamin D analogues (e.g. calcitriol) should be discontinued 1 week prior to initiation of treatment. The recommended starting dose in children and adolescents aged 1 to 17 years is 0.8 mg/kg of body weight given every two weeks. Doses should be rounded to the nearest 10 mg. The maximum dose is 90 mg. After initiation of treatment with burosumab, fasting serum phosphate should be measured every 2 weeks for the first month of treatment, every 4 weeks for the following 2 months and thereafter as appropriate. Fasting serum phosphate should also be measured 4 weeks after any dose adjustment. If fasting serum phosphate is within the reference range for age, the same dose should be maintained. The recommended starting dose in adults is 1.0 mg/kg of body weight, rounded to the nearest 10 mg up to a maximum dose of 90 mg, given every 4 weeks. After initiation of treatment with burosumab, fasting serum phosphate should be measured every 2 weeks for the first month of treatment, every 4 weeks for the following 2 months and thereafter as appropriate. Fasting serum phosphate should be measured 2 weeks after the previous dose of burosumab. If serum phosphate is within the normal range, the same dose should be continued. For subcutaneous use.

**CONTRAINDICATIONS:** Hypersensitivity to the active substance or to any of the excipients listed in section 6.1 of Package Insert. Concurrent administration with oral phosphate, active vitamin D analogs (see section 4.5 of Package Insert). Fasting serum phosphate above the normal range for age due to the risk of hyperphosphatemia (see section 4.4 of Package Insert). Patients with severe renal impairment or end stage renal disease.

**WARNINGS AND PRECAUTIONS:** Traceability: In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded within the patient's records. Ectopic mineralization: Ectopic mineralization, as manifested by nephrocalcinosis, has been observed in patients with XLH treated with oral phosphate and active vitamin D analogs; these medicinal products should be stopped at least 1 week prior to initiating burosumab treatment (see section 4.2 of Package Insert). Hyperphosphataemia: Levels of fasting serum phosphate should be monitored due to the risk of hyperphosphatemia. Serum parathyroid hormone: Increases in serum parathyroid hormone have been observed in some XLH patients during treatment with burosumab. Periodic measurement of serum parathyroid hormone is advised. Injection site reactions: Administration of burosumab may result in local injection site reactions. Administration should be interrupted in any patient experiencing severe injection site reactions (see section 4.8 of Package Insert) and appropriate medical therapy administered. Hypersensitivity: Burosumab must be discontinued if serious hypersensitivity reactions occur and appropriate medical treatment should be initiated. Excipient with known effect: This medicine contains 45.91 mg of sorbitol in each vial which is equivalent to 45.91 mg/ml.

**UNDESIRABLE EFFECTS:** The most common (>10%) adverse drug reactions reported in pediatric patients treated for up to 64 weeks during clinical trials were: injection site reactions (56%), cough (56%), headache (50%), pyrexia (43%), pain in extremity (40%), vomiting (39%), tooth abscess (35%), vitamin D decreased (32%), diarrhea (25%), rash (24%), nausea (15%), constipation (11%), dental caries (11%) and myalgia (11%). The most common adverse drug reactions reported in adult patients during clinical trials were: back pain (23%), headache (21%), tooth infection (19%), restless legs syndrome (13%), muscle spasms (12%), vitamin D decrease (15%) and dizziness (11%).

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