

CRYSVITA® (burosumab) dosing Factsheet for adults with X-linked hypophosphataemia (XLH)

CRYSVITA® is indicated for the treatment of X-linked hypophosphataemia (XLH), in adult and pediatric patients 1 year of age and older.¹



Starting CRYSVITA®

- » Discontinue oral phosphate and active vitamin D analogs 1 week prior to initiation of treatment. Fasting serum phosphorus concentration should be below the reference range for age prior to initiation of treatment.¹

Starting dose in adults¹

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**.¹

Measurement of fasting serum phosphate¹

- » After initiation of treatment with CRYSVITA, assess fasting serum phosphorus on a monthly basis, measured 2 weeks post-dose, for the first 3 months of treatment, and thereafter as appropriate. If serum phosphorus is within the normal range, continue with the same dose.
- » Fasting serum phosphorus concentration should be below the reference range for age prior to initiation of treatment.¹

SAMPLE STARTING DOSE CALCULATION – ADULTS (≥18 YEARS)

Patient weight (kg) x Recommended starting dose (1.0 mg/kg)

Example: 72 kg x 1.0 mg/kg = 72 mg (**Round to nearest 10 mg**)
Starting dose CRYSVITA® = 70 mg (**The maximum dose is 90 mg**)



CRYSVITA® vials¹

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 a 1 mL solution.



Missed dose¹

If a patient misses a dose, CRYSVITA® should be resumed as soon as possible at the prescribed dose.

REFERENCE 1. CRYSVITA® (burosumab). Based on Singapore Package Insert. Kyowa Kirin Asia Pacific Pte Ltd; 2021.



For X-linked hypophosphataemia (XLH)

Abbreviated Package Insert of CRYSVITA® Solution for Injection 10 mg/1mL, 20mg/1mL, or 30 mg/1mL

Composition:

Burosumab.

Indication:

Treatment of X-linked hypophosphatemia (XLH) in adult and pediatric patients 1 yr of age and older.

Dosage & Administration:

Pediatric: BW<10 kg: 1 mg/kg (rounded to the nearest 1 mg), administered q2w. BW>10 kg: starting dose is 0.8 mg/kg (rounded to the nearest 10 mg), administered q2w. The starting dose should be between 10 to 90 mg. Dose may be increased to ~2mg/kg (max 90 mg), administered q2w to achieve normal serum P. Adult: 1 mg/kg (rounded to the nearest 10 mg, max dose: 90 mg), administered q4w.

Contraindications:

Concomitant use with oral phosphate &/or active vit D analogs due to the risk of hyperphosphatemia; serum phosphorus is within above the normal range for age; severe renal impairment/ESRD due to abnormal mineral metabolism.

Precautions:

Hypersensitivity; hyperphosphatemia & risk of nephrocalcinosis; injection site reactions; Pregnancy & lactation; Pediatric <1 yr of age; Elderly; Renal impairment.

Common adverse reactions:

For pediatric: pyrexia; injection site reactions, cough, vomiting; pain in extremity; headache; tooth abscess; dental caries.

For adults: back pain; headache; tooth infection; restless leg syndrome; vitamin D decreased; dizziness; constipation; muscle spasms; increase serum P.

Interaction:

Oral phosphate and active vit D analogs.

P/P:

Injection: 10 mg/mL, 20 mg/mL, or 30 mg/mL in a single-dose vial.

Approved version of package insert: Jan 2020

Please refer to the full prescribing information before prescribing. Further information is available upon request.