CRYSVITA® (burosumab) dosing factsheet for pediatric patients 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®

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.[1]

Measurement of fasting serum phosphate

After initiation of treatment with CRYSVITA®, measure fasting serum phosphorus every 4 weeks for the first 3 months of treatment, and thereafter as appropriate. If serum phosphorus is above the lower limit of the reference range for age and below 5 mg/dL, continue treatment with the same dose. Fasting serum phosphate should also be measured 4 weeks after any dose adjustment. Fasting serum phosphorus concentration should be below the reference range for age prior to initiation of treatment.[1]

Table 1 : Pediatric Dose Schedule for Stepwise Dose Increase

Body Weight (kg)	Starting Dose (mg)	First Dose Increase to (mg)	Second Dose Increase to (mg)
10-14	10	15	20
15-18	10	20	30
19-31	20	30	40
32-43	30	40	60
44-56	40	60	80
57-68	50	70	90
69-80	60	90	90
81-93	70	90	90
94-105	80	90	90
≥106	90	90	90

Table 2 : Pediatric Dose Schedule for Re-Initiation of Therapy

Previous Dose (mg)	Re-Initiation Dose (mg)
10	5
15	10
20	10
30	10
40	20
50	20
60	30
70	30
80	40
90	40

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.

Dose increase[1]

If serum phosphorus is below the reference range for age, the dose may be increased stepwise up to approximately 2 mg/kg, administered every two weeks (maximum dose of 90 mg) according to the dosing schedule shown in Table 1. Reassess fasting serum phosphorus level 4 weeks after dose adjustment.

Dose decrease[1]

If serum phosphorus is above 5 mg/dL, withhold the next dose and reassess the serum phosphorus level in 4 weeks. The patient must have serum phosphorus below the reference range for age to reinitiate CRYSVITA. Once serum phosphorus is below the reference range for age, treatment may be restarted according to the dose schedule shown in Table 2. Reassess serum phosphorus level 4 weeks after dose adjustment.

Missed dosing[1]

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

The maximum dose is 90 mg irrespective of weight.

CRYSVITA® should not be adjusted more frequently than every 4 weeks.[1]

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). Based on Singapore Package Insert. Kyowa Kirin Asia Pacific Pte Ltd; 2021.

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CRYSVITA® burosumab

For X-linked hypophosphataemia (XLH)

CRYSVITA® Abbreviated Product Information

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

INDICATIONS AND USAGE

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

DOSAGE AND ADMINISTRATION

CRYSVITA® is administered by subcutaneous injection and should be administered by a healthcare provider. 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. For pediatric patients (1 to less than 18 years of age), the recommended starting dose regimen is 0.8 mg/kg of body weight, rounded to the nearest 10 mg, administered every two weeks. The minimum starting dose is 10 mg up to a maximum dose of 90 mg. After initiation of treatment with CRYSVITA®, measure fasting serum phosphorus every 4 weeks for the first 3 months of treatment, and thereafter as appropriate. For adult patients (18 years of age and older), the recommended dose regimen is 1 mg/kg body weight, rounded to the nearest 10 mg up to a maximum dose of 90 mg, administered every four weeks.

CONTRAINDICATIONS

Do not use CRYSVITA® with oral phosphate and active vitamin D analogs. Do not initiate CRYSVITA® treatment if serum phosphorus is within or above the normal range for age. CRYSVITA® is contraindicated in patients with severe renal impairment or end stage renal disease because these conditions are associated with abnormal mineral metabolism.

WARNINGS AND PRECAUTIONS

Hypersensitivity: hypersensitivity reactions (e.g. rash, urticaria) have been reported in patients with CRYSVITA®. Discontinue CRYSVITA® if serious hypersensitivity reactions occur and initiate appropriate medical treatment. **Hyperphosphataemia and Risk of Nephrocalcinosis:** increases in serum phosphorus to above the upper limit of normal may be associated with an increased risk of nephrocalcinosis. For patients already taking CRYSVITA®, dose interruption and/or dose reduction may be required based on a patient's serum phosphorus levels. Injection Site Reactions: administration of CRYSVITA® may result in local injection site reactions. Discontinue CRYSVITA® if severe injection site reactions occur and administer appropriate medical treatment.

ADVERSE REACTIONS

Adverse reactions (>10%) reported in paediatric patients during clinical trials were: injection site reactions, cough, headache, pyrexia, pain in extremity, vomiting, tooth abscess, vitamin D decreased, diarrhoea, rash, nausea, constipation, dental caries, dizziness and myalgia. Adverse reactions (>5%) reported in adult patients during clinical trials were: back pain, headache, tooth infection, restless legs syndrome, vitamin D decrease and dizziness, constipation and blood phosphorus increased.

Product is approved in selected markets and local approved prescribing information may differ.
Please refer to local approval status and prescribing information.

This material is for Healthcare Professionals Only.

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