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 moni-toring of serum calcium and phosphate. For patients who weigh less than 10kg, the recommended starting dose is 1mg/kg of body weight, rounded to the nearest 1mg, administered every two weeks. For patients who weigh 10kg and greater, the recommended starting dose regimen is 0.8mg/kg of bo dy weight, rounded to the nearest 10mg, administered every two weeks. The minimum starting dose is 10mg up to a maximum dose of 90mg.[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

Dose increase[1]

For patients who weigh less than 10kg, if serum phosphate is below the reference range for age, the dose may be increased to 1.5mg/kg, rounded to the nearest 1mg, administered every two weeks. If additional dose increases are needed, the dose may be increased to the maximum dose of 2mg/kg, rounded to the nearest 1mg, administered every two weeks. For patients who weigh 10kg or greater, if serum phosphate is below the reference range for age, the dose may be increased stepwise up to approximately 2mg/kg, administered every two weeks (maximum dose of 90mg) 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 5mg/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, for patients who weigh less than 10kg, restart CRYSVITA® at 0.5mg/kg of body weight, rounded to the nearest 1mg, administered every two weeks. For patients who weigh 10kg or more, restart CRYSVITA® 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.

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.

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 Hong Kong Package Insert. Kyowa Kirin Hong Kong Co., Ltd. 2020.

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CRYSVITA®
burosumab

For X-linked hypophosphataemia (XLH)

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

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