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 adults[1]

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 phosphate[1]

» 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® vials[1]

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 dose[1]

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.

PLEASE REFER TO THE FULL PRESCRIBING INFORMATION BEFORE PRESCRIBING.
This material is for Healthcare Professionals Only.

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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.

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