

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; (Date of revision : FEB2023)



For X-linked hypophosphataemia (XLH)

CRYSVITA® Abbreviated Product Information

CRYSVITA® (burosumab). Based on Singapore Package Insert. Kyowa Kirin Asia Pacific Pte Ltd; (Date of Revision: FEB 2023)

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/or active vitamin D analogs (e.g. calcitriol, paricalcitol, doxercalciferol, calcifediol) 1 week prior to initiation of treatment. Fasting serum phosphorus concentration should be below the reference range for age prior to initiation of treatment. The maximum volume of CRYSVITA per injection is 1.5 mL. If multiple injections are required, administer at different injection sites.

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. 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. Follow dose adjustment schedule below to maintain serum phosphorus within the reference range for age.

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. 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.

CONTRAINDICATIONS

CRYSVITA is contraindicated:

- In concomitant use with oral phosphate and/or active vitamin D analogs (e.g. calcitriol, paricalcitol, doxercalciferol, calcifediol) due to the risk of hyperphosphatemia
- When serum phosphorus is within or above the normal range for age
- 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. **Hyperphosphatemia 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

The following adverse reactions are described below and elsewhere in the labeling: Hypersensitivity, Hyperphosphatemia and Risk of Nephrocalcinosis and Injection Site Reactions.

Adverse reactions (≥10%) reported in paediatric patients during clinical trials were: Pyrexia, Injection site reaction, Cough, Vomiting, Pain in extremity, Headache, Tooth abscess, Dental caries, Diarrhea, Vitamin D decreased, Constipation, Rash, Nausea, Myalgia, Toothache and Dizziness.

Adverse reactions (>5%) reported in adult patients during clinical trials were: Back pain, Headache, Tooth infection, Restless legs syndrome, Vitamin D decreased, Dizziness, Muscle spasms, Constipation and Blood phosphorus increased.

Please refer to the full prescribing information before prescribing.

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



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