

September 03, 2021

New Medicine Approved for the Treatment of X-linked Hypophosphatemia (XLH)¹

Crysvita® (burosumab) approved by the Australian Therapeutic Goods Administration for the treatment of XLH in Adults, Adolescents and Children 1 year of age or older.¹

Kyowa Kirin Australia today announced that Crysvita® has been approved by the Therapeutic Goods Administration (TGA) for the treatment of XLH in adults, adolescents and children 1 year of age or older.¹

“Crysvita® is the first new kind of medicine for the treatment of XLH in more than forty years², and the science shows that it actively targets the cause of the disease,”^{1,3} said General Manager of Kyowa Kirin Australia, Simon Dawson.

“Whilst the registration of Crysvita® is a major milestone for our company, our focus is now on securing PBS reimbursement so that Australians living with XLH can be guaranteed long-term affordable access to this important medicine,” said Mr Dawson.

XLH is a progressive and life-long disease resulting in painful and debilitating abnormalities in the bones, joints, muscles and teeth.^{3,5} It is a rare genetic disease³⁻⁵, estimated to affect fewer than 1300 Australians⁶⁻⁸, however it's the most common form of hereditary rickets.^{9,10} It can sometimes appear in individuals with no family history of the disease but is usually passed down from a parent carrying the defective gene.¹¹ The genetic defect, located on the X-chromosome, causes an excessive loss of phosphate through the urine and poor absorption from the gut, resulting in chronically low levels of phosphate in the blood.¹² Phosphate is a key mineral needed for maintaining the body's energy levels, muscle function,¹³ and healthy bones and teeth.^{3,14} XLH is not immediately life-threatening but its burden is life-long and progressive, leading to diminished quality of life¹⁵ as well as a reduction in survival relative to controls.¹⁶ While there is no cure for XLH, therapies aimed at helping to restore phosphate to normal levels within the body may help to improve the symptoms of the disease.¹¹

Crysvita® is a recombinant human monoclonal IgG1 antibody that binds to and inhibits the biological activity of fibroblast growth factor 23 (FGF23), present in excess in XLH.^{1,3} Neutralisation of FGF23 by Crysvita® increases renal reabsorption of phosphate and the serum concentration of 1, 25 dihydroxy-Vitamin D.^{1,3}

Kyowa Kirin is a research-based life sciences company. The company leverages leading-edge biotechnologies centred on antibody technologies to discover innovative new medicines that address unmet medical needs. Crysvita® is the second medicine from Kyowa Kirin to be approved for use in Australia.¹⁷

▼ This medicinal product is subject to additional monitoring in Australia. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at www.tga.gov.au/reporting-problems.

MINIMUM PRODUCT INFORMATION CRYSVITA® (burosumab) solution for injection

THERAPEUTIC INDICATION: CRYSVITA® (burosumab) is indicated for the treatment of X-linked hypophosphataemia (XLH) in adults, adolescents and children 1 year of age or older. **DOSE AND**

ADMINISTRATION: The recommended starting dose regimen for paediatrics (children 1-11yrs and adolescents 12-17yrs) is 0.8 mg/kg of body weight, rounded to the nearest 10 mg, every 2 weeks, up to a maximum dose of 90 mg. The recommended dose regimen in adults (18yrs and older) is 1 mg/kg of body weight, rounded to the nearest 10 mg up to a maximum dose of 90 mg, administered every 4 weeks. Treatment should be initiated and monitored by specialist medical practitioners experienced in the management of patients with metabolic bone disease. Fasting serum phosphate concentration should be below the reference range for age prior to initiation of treatment. CRYSVITA® is administered by subcutaneous injection and should be administered by a healthcare provider. The maximum volume of CRYSVITA® per injection site is 1.5 mL. If multiple injections are required, administer at different injection sites. **CONTRAINDICATIONS:** Hypersensitivity to CRYSVITA® or to any of the excipients. Concurrent administration with oral phosphate and / or active vitamin D analogues. Serum phosphate level within or above the normal range for age at initiation of treatment. Severe renal impairment or end stage renal disease. **PRECAUTIONS:** Discontinue oral phosphate and active vitamin D analogues at least 1 week prior to initiating CRYSVITA® treatment. Monitor for signs and symptoms of nephrocalcinosis, hyperphosphatemia, ectopic mineralisation, and serious hypersensitivity reactions. Administration should be interrupted in any patient experiencing severe injection site reactions. Discontinue if serious hypersensitivity reaction occurs. Monitoring for signs and symptoms of nephrocalcinosis due to ectopic mineralisation, e.g. by renal ultrasonography, is recommended at the start of treatment and every 6 months for the first 12 months of treatment, and annually thereafter. Monitoring of urine calcium and phosphate is suggested every 3 months. Monitoring of plasma alkaline phosphatase, calcium, parathyroid hormone (PTH) and creatinine is recommended every 6 months (every 3 months for children 1 - 2 years) or as indicated.

INTERACTIONS: Concurrent administration of CRYSVITA® with oral phosphate and active vitamin D analogues is contraindicated as it may cause an increased risk of hyperphosphatemia and hypercalcaemia. Caution should be exercised when combining CRYSVITA® with calcimimetic medicinal products. **ADVERSE EFFECTS:** Very common adverse reactions (>10%) reported in paediatric patients (≥1-17yrs) during clinical trials who had received at least 1 dose of CRYSVITA® were: injection site reactions, cough, headache, pyrexia, pain in extremity, vomiting, tooth abscess, vitamin D decreased, diarrhoea, rash, nausea, constipation, dental caries and myalgia. Common adverse reactions (≤10%) reported in paediatric patients ≥1 year of age during clinical trials who had received at least 1 dose of CRYSVITA® were: dizziness and blood phosphorus increased. Very common adverse reactions (>10%) reported in adult patients (≥18yrs) who had received at least 1 dose of CRYSVITA® during clinical trials were: back pain, headache, tooth infection, restless legs syndrome, muscle spasms, vitamin D decrease and dizziness. Common adverse reactions (≤10%) reported in adult patients who had received at least 1 dose of CRYSVITA® during clinical trials were: constipation and blood phosphorus increased. Content based on full CRYSVITA® Product Information. Date Approved: 03Sept2021.

Please review full Product Information before prescribing. Product Information is available at: <https://www.kyowakirin.com/australia/our-medicines/doc/crysvita-product-information-leaflet.pdf>

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www.kyowakirin.com/australia. enquiry.kkau@kyowakirin.com. KKAU-XLH-2108062. Date of preparation August 2021.

PBS Information: This medicine is not available through the PBS.

Please review the Consumer Medicines Information [here](#) or the full Product Information [here](#) for further safety information.

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