PRESCRIBING GUIDE FOR AUSTRALIAN HEALTH CARE PROFESSIONALS

KYOWA KIRIN

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▼ 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.[1]

Adverse events can also be reported at pv.kkau.2r@kyowakirin.com

Please report any product quality issues to enquiry.kkau@kyowakirin.com

What is CRYSVITA® (burosumab)?

CRYSVITA® is a recombinant fully human monoclonal antibody (IgG1) that binds to and inhibits the excess activity of FGF23[1]

By inhibiting FGF23 activity, CRYSVITA® increases tubular reabsorption of phosphate from the kidney and increases serum concentration of $1,25(OH)_2D$, so increasing serum phosphate levels[1]

CRYSVITA® Indication

CRYSVITA® is indicated for the treatment of X-linked hypophosphataemia (XLH) in adults, adolescents and children 1 year of age or older[1]

CRYSVITA® PBS LISTING[2]

Date of listing: 1 November 2022

Condition: X-linked hypophosphataemia

PBS Indication: X-linked hypophosphataemia

Category / program: Section 100
(Highly Specialised Drugs Program)

Authority Required: Telephone/online PBS Authorities system

Prescriber type: Medical Practitioners

Treatment phase: Initial treatment – New patient

Clinical criteria:

Patient must have a documented confirmation of PHEX pathogenic variant;

OR

Patient must have a confirmed diagnosis of X-Linked hypophosphataemia by the presence of all of the following:

(i) a serum phosphate concentration below the age adjusted lower limit of normal;

(ii) current or historical (for those with growth plate fusion) radiographic X-ray evidence of rickets;

(iii) elevated (or inappropriately normal) serum or plasma FGF-23 levels of above the mean of the assay-specific reference range;

(iv) renal phosphate wasting demonstrated by a ratio of tubular maximum reabsorption rate of phosphate to glomerular filtration rate (TmP/GFR) according to age specific normal ranges using the second morning urine void and paired serum sample measuring phosphate and creatinine

Treatment criteria:

Must be treated by a medical practitioner identifying as one oaf the following specialists:

(i) paediatric endocrinologist

(ii) paediatric nephrologist

(iii) endocrinologist

(iv) nephrologist

Prescribing Instructions:

- At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI).
  - A separate authority prescription form must be completed for each strength requested.
  - Up to a maximum of 5 repeats will be authorised.
- Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records

Administrative advice:

- Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
- No increase in the maximum number of repeats may be authorised.
- Special Pricing Arrangements apply

Treatment phase: Continuing treatment

Clinical criteria:

Patient must have previously received PBS-subsidised treatment with this drug for this condition

AND

Patient must have achieved normalisation in serum phosphate levels

AND

Patient must have radiographical evidence of stabilisation / improvement in rickets in patients without growth plate fusion

Treatment criteria:

Must be treated by a medical practitioner identifying as one of the following specialists:

(i) paediatric endocrinologist
(ii) paediatric nephrologist
(iii) endocrinologist
(iv) nephrologist

Prescribing Instructions:

- Where adequate response to treatment with burosumab cannot be demonstrated, the treating physician must confirm that continuing therapy has been determined to be clinically required by a second specialist physician with expertise in the treatment of X-linked hypophosphataemia
- At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI).
  - A separate authority prescription form must be completed for each strength requested.
  - Up to a maximum of 5 repeats will be authorised.
- Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records

Administrative advice:

- Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
- No increase in the maximum number of repeats may be authorised.
- Special Pricing Arrangements apply

Treatment phase: Transitioning from non-PBS to PBS-subsidised supply – Grandfather arrangements

Clinical criteria:

Patient must have previously received non-PBS subsidised treatment with this drug for this condition prior to 1 November 2022.

AND

Patient must have a documented confirmation of PHEX pathogenic variant;

OR

Patient must have a diagnosis of X-Linked hypophosphataemia by the presence of all of the following:

(i) a serum phosphate concentration below the age adjusted lower limit of normal;
(ii) current or historical (for those with growth plate fusion) radiographic X-ray evidence of rickets;
(iii) elevated (or inappropriately normal) serum or plasma FGF-23 levels of above the mean of the assay-specific reference range;
(iv) renal phosphate wasting demonstrated by a ratio of tubular maximum reabsorption rate of phosphate to glomerular filtration rate (TmP/GFR) according to age specific normal ranges using the second morning urine void and paired serum sample measuring phosphate and creatinine

AND

Patient must have achieved normalisation in serum phosphate levels

AND

Patient must have radiographical evidence of stabilisation/ improvement in rickets in patients without growth plate fusion

Treatment criteria:

Must be treated a medical practitioner identifying as one of the following specialists:

(i) paediatric endocrinologist
(ii) paediatric nephrologist
(iii) endocrinologist
(iv) nephrologist

Prescribing Instructions:

- Where adequate response to treatment with burosumab cannot be demonstrated, the treating physician must confirm that continuing therapy has been determined to be clinically required by a second specialist physician with expertise in the treatment of X-linked hypophosphataemia
- At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI).
  - A separate authority prescription form must be completed for each strength requested.
  - Up to a maximum of 5 repeats will be authorised.
- Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records

Administrative advice:

- Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.
- This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria
- Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
- No increase in the maximum number of repeats may be authorised.
- Special Pricing Arrangements apply

CRYSVITA® is listed on the Section 100 – Highly Specialised Drugs Program.

Full details on the S100 program can be found at https://www.pbs.gov.au/info/browse/section-100/s100-highly-specialised-drugs.

Authority is required for this item. Applications can be made via:

- Online PBS Authorities system: www.servicesaustralia.gov.au/HPOS or
- Telephone Services Australia: 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI).

A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

MEDICINAL PRODUCT medicinal product pack (Name, form & strength and pack size)	**PBS item code**	**Maximum quantity (packs)**	**Maximum quantity (units)**	**No. of repeats**	**Available brands**
BUROSUMAB					
BUROSUMAB 10 mg/mL injection, 1 mL vial	13140N (HSD Public) 13163T (HSD Private)	1	1	5	Crysvita®
BUROSUMAB 20 mg/mL injection, 1 mL vial	13145W (HSD Public) 13136J (HSD Private)	1	1	5	
BUROSUMAB 30 mg/mL injection, 1 mL vial	13155J (HSD Public) 13154H (HSD Private)	1	1	5	

Full details on how to request an Authority Prescription online can be found at:

https://www.servicesaustralia.gov.au/request-authority-using-online-pbs-authorities-hpos?context=22866

Treatment should be initiated and monitored by specialist medical practitioners experienced in the management of patients with metabolic bone disease.[1]

** For **full dosing schedule and dose adjustment protocol**, please refer to CRYSVITA® (burosumab) DOSING AND ADMINISTRATION GUIDE IN PAEDIATRIC AND ADULT PATIENTS (KKAU-XLH-2207141) available from Kyowa Kirin Australia.*

CRYSVITA® DOSING SCHEDULE IN PAEDIATRIC PATIENTS[1]

All patients should discontinue oral phosphate and active vitamin D analogues (e.g. calcitriol, paricalcitol, doxercalciferol, calcifediol) 1 week prior to initiation of CRYSVITA® treatment.

Vitamin D replacement or supplementation with inactive forms of vitamin D may be continued as per local guidelines

Fasting serum phosphate concentration should be below the reference range for age prior to initiation of treatment.

Dosing in children (≥1 year) is every 2 weeks.

Recommended starting dose: 0.8 mg/kg of body weight [up to a maximum dose of 2mg/kg], rounded to the nearest 10 mg. The minimum starting dose is 10 mg up to a maximum dose of 90 mg.

After initiating CRYSVITA®, measure fasting serum phosphate every 4 weeks for the first 3 months of treatment, and thereafter as appropriate. If serum phosphate is within the reference range for age, continue with the same dose.

CRYSVITA® DOSING SCHEDULE IN ADULT PATIENTS[1]

All patients should discontinue oral phosphate and active vitamin D analogues (e.g. calcitriol, paricalcitol, doxercalciferol, calcifediol) 1 week prior to initiation of CRYSVITA® treatment.

Fasting serum phosphate concentration should be below the reference range for age prior to initiation of treatment.

Dosing in adult patients (≥18 years of age) is every 4 weeks

Recommended starting dose: 1 mg/kg of body weight, rounded to the nearest 10 mg up to a maximum dose: 90 mg

After initiating CRYSVITA®, measure fasting serum phosphate every 4 weeks. Measure at 2 weeks post-dose, for the first 3 months of treatment, and thereafter as appropriate. If serum phosphate is within the normal range, continue with the same dose.

** For full dosing schedule and dose adjustment protocol, please refer to CRYSVITA® (burosumab) DOSING AND ADMINISTRATION GUIDE IN PAEDIATRIC AND ADULT PATIENTS (KKAU-XLH-2207141) available from Kyowa Kirin Australia.*

General Dosing Example

Sample Starting Dose Calculation – Paediatric (1 to <18 years)
Patient weight (kg) x Recommended starting dose (0.8mg/kg)

Child initiation 26kg

- Patient weight (kg) x Recommended starting dose (0.8mg/kg)
- Example: 26 kg x 0.8 mg/kg = 20.8 mg (Round to nearest 10 mg)
- Starting dose CRYSVITA® = 20 mg
- Authority Required: Script 1: 2x 20mg vials plus 5 repeats

Child continuation 33kg

- Patient weight (kg) x Recommended starting dose (0.8mg/kg)
- Example: 33 kg x 0.8 mg/kg = 26.4 mg (Round to nearest 10 mg)
- Continuation dose CRYSVITA® = 30 mg
- Authority Required: Script 1: 2x 30mg vials plus 5 repeats

Child grandfathering 59kg

- Patient weight (kg) x Recommended starting dose (0.8mg/kg)
- Example: 59 kg x 0.8 mg/kg = 47.2 mg (Round to nearest 10 mg)
- Grandfathering dose CRYSVITA® = 50 mg
- Authority Required: Script 1. 2x 30 mg vials plus 5 repeats
  Script 2. 2x 20 mg vials plus 5 repeats

General Dosing Example

Sample Starting Dose Calculation: Adult patient (≥18 years of age)
Patient weight (kg) x Recommended starting dose (1 mg/kg)

Adult initiation 72kg

- Patient weight (kg) x Recommended starting dose (1 mg/kg)
- Example: 72 kg x 1 mg/kg = 72 mg (Round to nearest 10 mg)
- Starting dose CRYSVITA® = 70 mg
- Authority Required: Script 1: 2x 30mg vials plus 5 repeats
  Script 2: 1x 10mg vial plus 5 repeats

Adult continuation 83kg

- Patient weight (kg) x Recommended starting dose (1 mg/kg)
- Example: 83 kg x 1 mg/kg = 83 mg (Round to nearest 10 mg)
- Continuation dose CRYSVITA® = 80 mg
- Authority Required: Script 1: 2x 30mg vials plus 5 repeats
  Script 2: 1x 20mg vial plus 5 repeats

Adult grandfathering 95kg

- Patient weight (kg) x Recommended starting dose (1 mg/kg)
- Example: 95 kg x 1 mg/kg = 95 mg (Round to nearest 10 mg)
- Grandfathering dose CRYSVITA® = 90 mg (maximum dose allowable)
- Authority Required: Script 1: 3x 30mg vials plus 5 repeats

CRYSVITA® will be dispensed by pharmacies who hold an account with Healthcare Logistics (HCL).

Patients taking their prescription to their preferred pharmacy will need to ensure the pharmacy has an account with HCL.

HCL account applications can be requested from Kyowa Kirin Australia or downloaded from https://hcl.com.au/.

Helpful Information

- It is unlikely that pharmacies will hold stock of CRYSVITA®, therefore patients will need to drop off their CRYSVITA® prescription several days in advance of their next administration to ensure stock is ordered and can be dispensed when required.
- CRYSVITA® requires refrigeration, so it is recommended that patients take appropriate measures to ensure their dispensed prescription remains at 2-8°C prior to their injection.
- Please refer to accompanying documents:
  - CRYSVITA® (burosumab) Access Instructions for Patients (KKAU-XLH-2209203)
  - CRYSVITA® (burosumab) Access Instructions for Pharmacies (KKAU-XLH-2209204)

  1. After making the decision to prescribe CRYSVITA® for your patient, please provide both documents to your patient.
  2. Please ask the patient to provide the document *"CRYSVITA® (burosumab) Instructions for Pharmacies"* to their preferred pharmacy to facilitate CRYSVITA® dispensing.

CRYSVITA® should be administered subcutaneously by a healthcare provider.

- Inject in the upper arm, abdomen, buttock or thigh.
- Do not inject into moles, scars, or areas where the skin is tender, bruised, red, hard, or not intact.

The maximum volume of CRYSVITA® per injection site is 1.5 mL. If more than 1.5 mL is required on a given dosing day, the total volume of CRYSVITA® should be split and administered at two different injection sites.

Injections sites should be rotated and carefully monitored for signs of potential reactions.

** For full CRYSVITA® injection guide, please refer to "CRYSVITA® (BUROSUMAB) INJECTION: Instructions for Use" (KKAU-XLH-2209142) available from Kyowa Kirin Australia.*

CRYSVITA® Storage[1]

- Visually inspect CRYSVITA® for particulate matter and discoloration prior to administration.
- CRYSVITA® is a sterile, preservative-free, clear to slightly opalescent and colourless to pale brown-yellow solution for subcutaneous injection.
- Do not use if the solution is discoloured or cloudy or if the solution contains any particles or foreign particulate matter
- The product is available as one single-dose vial per carton in the following strengths : 10, 20, 30 mg/mL.

Store in original package to protect from light until use, under refrigerated conditions at 2°C to 8°C.

Do not freeze or shake. Do not use CRYSVITA® after the expiry date which is stated on the package and label. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Please report any product quality issues to enquiry.kkau@kyowakirin.com

CRYSVITA® Safety Reporting

Healthcare professionals are asked to report any suspected adverse events at www.tga.gov.au/reporting-problems [1]

Adverse events can also be reported at pv.kkau.2r@kyowakirin.com

Kyowa Kirin Resources

Kyowa Kirin Australia

Kyowa Kirin Australia Pty Ltd
68 York Street, Sydney, NSW 200
https://www.kyowakirin.com/australia/index.html
enquiry.kkau@kyowakirin.com

Downloadable CRYSVITA® resources

https://www.crysvita.asia/australia/home/
Access for HCPs only. Registration is required

Patient Advocacy

XLH Australia

https://xlhaustralia.com/

Rare Voices Australia

https://rarevoices.org.au/

Genetic Alliance

https://www.geneticalliance.org.au/

References:

1. Australian Product Information for Crysvita® (burosumab) approved Sept 2021. Available at: https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2021-PI-02101-1&d=20220917172310101 Last accessed September 2022.
2. Australian Government. Schedule of Pharmaceutical Benefits. 2022. Available at: https://www.pbs.gov.au/pbs/home

Minimum Prescribing Information:

CRYSVITA® (burosumab)

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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 phosphate 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 phosphate increased. Content based on full CRYSTVITA® Product Information. Date Approved: 10 Sept 2021.

Full PI Available at: https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2021-PI-02101-1&d=20220917172310101 Last accessed October 2022.

PBS INFORMATION: This product is listed on the PBS as a Section 100 item. Refer to PBS Schedule for full authority information.

CRYSVITA® burosumab

KYOWA KIRIN

Kyowa Kirin Australia Pty Ltd, 68 York Street, Sydney.
https://www.kyowakirin.com/australia/index.html.
Date of Preparation October 2022. KKAU-XLH-2209202
Report adverse events to pv.kkau.2r@kyowakirin.com

CRYSVITA® (BUROSUMAB) INFORMATION FOR PATIENTS

Your doctor has prescribed for you a medicine called CRYSVITA (burosumab) to treat X-linked hypophosphataemia (XLH).

Please consult with your doctor for any questions relating to XLH or its management.
CRYSVITA should be given by injection by a trained healthcare provider. The dose is based on your body weight. Your doctor will work out the right dose for you.
You can find more information about CRYSVITA in the following resources. Copies can be requested from your doctor:

- CRYSVITA Consumer Medicine Information (CMI)
  - https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent=&id=CP-2021-CMI-02100-1&d=20220923172310101
- CRYSVITA starter guide for adults
- CRYSVITA starter guide for children
- CRYSVITA starter guide for parent & carers

IMPORTANT INFORMATION ABOUT YOUR CRYSVITA PRESCRIPTION

1. Pharmacy dispensing
   a. Your CRYSVITA prescription can be dispensed from a hospital pharmacy or a retail pharmacy as directed by your doctor
      i. The pharmacy must have an account with Health Care Logistics (HCL), so that they can order CRYSVITA for you.
      ii. Please provide the sheet *CRYSVITA® (burosumab) Instructions for Pharmacies* to your preferred pharmacy to check that they will be able to fulfil your prescription.
   b. Your pharmacy is unlikely to hold a regular supply of CRYSVITA, so you will need to give them a few days warning before your next dose is due so that they can order it in for you. *Speak to your pharmacist to work out the optimal way for this to be done on a regular basis.*
   c. CRYSVITA should be kept refrigerated – between 2-8°C.
   d. Please take your CRYSVITA dose directly to the health care practice where you will be receiving the injection.

Kyowa Kirin Australia Pty Ltd, 68 York Street, Sydney.
https://www.kyowakirin.com/australia/index.html.
Date of Preparation October 2022. KKAU-XLH-2209203
Report adverse events to pv.kkau.2r@kyowakirin.com

▼ 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.[1] **1.** Australian Product Information for Crysvita® (burosumab) approved Sept 2021. Available at: https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2021-PI-02101-1&d=20220917172310101 Last accessed September 2022.

CRYSVITA® (BUROSUMAB) ACCESS INSTRUCTIONS FOR PHARMACIES

Dear Pharmacist,

Your patient has been prescribed CRYSVITA® (burosumab) for the treatment of X-linked hypophosphataemia.

CRYSVITA® is distributed by Healthcare Logistics (HCL) to pharmacies.

Healthcare Logistics
7 Dolerite Way, Pemulwuy, NSW, 2145
PO Box 6006, Seven Hills, NSW 2147
Tel -1300 364 586
Fax 1300 068 494
Email Client.Services@hcl.com.au

HCL account applications can be requested from Kyowa Kirin Australia or downloaded from https://hcl.com.au/

What is CRYSVITA®?

CRYSVITA® is a recombinant fully human monoclonal antibody (IgG1) that binds to and inhibits the excess activity of FGF23[1]

By inhibiting FGF23 activity, CRYSVITA® increases tubular reabsorption of phosphate from the kidney and increases serum concentration of $1,25(OH)_2D$, so increasing serum phosphate levels[1]

CRYSVITA® Indication

CRYSVITA® is indicated for the treatment of X-linked hypophosphataemia (XLH) in adults, adolescents and children 1 year of age or older[1]

CRYSVITA® PBS Listing[2]

Date of listing: 1 November 2022
Condition: X-linked hypophosphataemia
PBS Indication: X-linked hypophosphataemia
Category / program: Section 100 (Highly Specialised Drugs Program)
Authority Required: Telephone/online PBS Authorities system
Prescriber type: Medical Practitioners

CRYSVITA® - How Supplied[1]

- The product is available as one single-dose vial per carton in the following strengths: 10, 20, 30 mg/mL.
- Each pack contains 1 mL solution in a clear glass vial with butyl rubber stopper, and aluminium seal.

CRYSVITA® Storage[1]

- Visually inspect CRYSVITA® for particulate matter and discoloration prior to administration.
- CRYSVITA® is a sterile, preservative-free, clear to slightly opalescent and colourless to pale brown-yellow solution for subcutaneous injection.
- Do not use if the solution is discoloured or cloudy or if the solution contains any particles or foreign particulate matter

Store in original package to protect from light until use, under refrigerated conditions at 2°C to 8°C.

Do not freeze or shake. Do not use CRYSVITA® after the expiry date which is stated on the package and label. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Further information

Further information can be supplied on request from the manufacturer, Kyowa Kirin Australia.

Kyowa Kirin Australia Pty Ltd,
68 York Street, Sydney.
https://www.kyowakirin.com/australia/index.html.
Enquiries: enquiry.kkau@kyowakirin.com
Report adverse events to pv.kkau.2r@kyowakirin.com

PBS INFORMATION: This product is listed on the PBS as a Section 100 item.
Refer to PBS Schedule for full authority information.

Please refer to the Full Prescribing Information Available at: https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2021-PI-02101-1&d=20220917172310101 Last accessed September 2022.

References:

1. Australian Product Information for Crysvita® (burosumab) approved Sept 2021. Available at: https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2021-PI-02101-1&d=20220917172310101 Last accessed September 2022.
2. Australian Government. Schedule of Pharmaceutical Benefits. 2022. Available at: https://www.pbs.gov.au/pbs/home

Kyowa Kirin Australia Pty Ltd, 68 York Street, Sydney.
https://www.kyowakirin.com/australia/index.html.
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