



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	340797	CRYSVITA burosumab 30 mg/mL solution for injection in a 5 mL vial
ARTG entry for	Medicine Registered	
Sponsor	Kyowa Kirin Australia Pty Ltd	
Postal Address	68 York St, Sydney, NSW, 2000 Australia	
ARTG Start Date	10/09/2021	
Product Category	Medicine	
Status	Active	
Approval Area	Drug Safety Evaluation Branch	



Medicine under additional monitoring

Conditions

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Products

1 . CRYSVITA burosumab 30 mg/mL solution for injection in a 5 mL vial

Product Type	Single Medicine Product	Effective Date	10/09/2021
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Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

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

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

This product is included in the Black Triangle Scheme

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Vial	Not recorded	36 Months	Store at 2 to 8 degrees Celsius	Neither child resistant closure nor restricted flow insert	Do not Freeze Refrigerate Protect from Light Do not Shake Store in Original Container

Pack Size/Poison information

Pack Size	Poison Schedule
1 x 5 mL vial	(S4) Prescription Only Medicine

Components

1 . CRYSVITA burosumab 30 mg/mL solution for injection in a 5 mL vial

Dosage Form	Injection, solution
Route of Administration	Subcutaneous clear to slightly opalescent, colourless to pale brownish-yellowish solution



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Visual Identification

Active Ingredients

burosumab **30 mg**

Other Ingredients (Excipients)

histidine
hydrochloric acid
methionine
polysorbate 80
sorbitol
water for injections

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