



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	319410	ALKINDI hydrocortisone 2 mg granules (in capsule) bottle
ARTG entry for	Medicine Registered	
Sponsor	Chiesi Australia Pty Ltd	
Postal Address	Suite 3 22 Gillman Street, Hawthorn East, VIC, 3123 Australia	
ARTG Start Date	18/08/2020	
Product Category	Medicine	
Status	Active	
Approval Area	Drug Safety Evaluation Branch	

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 . ALKINDI hydrocortisone 2 mg granules (in capsule) bottle

Product Type	Single Medicine Product	Effective Date	2/11/2021
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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

Replacement therapy of adrenal insufficiency

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	HDPE	3 Years	Store below 30 degrees Celsius	Not recorded	Store in Original Container Protect from Light

Pack Size/Poison information

Pack Size	Poison Schedule
50 capsules per bottle	(S4) Prescription Only Medicine

Components

1 . ALKINDI hydrocortisone 2 mg granules (in capsule) bottle

Dosage Form	Granules
Route of Administration	Oral
Visual Identification	The granules are white to off-white and contained in a transparent colourless size 00el hard capsule. The capsule is printed with INF-2.0 in green ink.

Active Ingredients

hydrocortisone	2 mg
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Other Ingredients (Excipients)

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ethylcellulose

hypromellose

magnesium stearate

microcrystalline cellulose

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