



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 386430 GLENBEX Calcipotriol (as monohydrate) 50 microgram/g and Betamethasone (as dipropionate) 500 microgram/g Foam Aerosol Can

ARTG entry for Medicine Registered
Sponsor Freyr Australia Pty Ltd
Postal Address 46 Dora Street, Blacktown, NSW, 2148
Australia
ARTG Start Date 2/06/2023
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 . GLENBEX Calcipotriol (as monohydrate) 50 microgram/g and Betamethasone (as dipropionate) 500 microgram/g Foam Aerosol Can

Product Type	Single Medicine Product	Effective Date	2/06/2023
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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

Topical treatment of psoriasis vulgaris in adults.

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Aerosol Can	Al	12 Months	Store below 25 degrees Celsius	Neither child resistant closure nor restricted flow insert	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule
2 x 60 g	(S4) Prescription Only Medicine
60 g	(S4) Prescription Only Medicine

Components

1 . GLENBEX Calcipotriol (as monohydrate) 50 microgram/g and Betamethasone (as dipropionate) 500 microgram/g Foam Aerosol Can

Dosage Form Foam
Route of Administration Topical
Visual Identification White to off-white opalescent liquid in a pressurised aluminium spray can with a valve and actuator. At administration it is a white to off-white foam

Active Ingredients

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betamethasone dipropionate

Equivalent: betamethasone

643 microgram/g

500 microgram/g

calcipotriol monohydrate

52.2 microgram/g

Other Ingredients (Excipients)

butane

d-alpha-tocopherol

isobutane

isopropyl alcohol

liquid paraffin

polyoxypropylene-11 stearyl ether

propane

white soft paraffin

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