




Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	388597	SPEVIGO spesolimab (rch) 450 mg in 7.5 mL concentrated solution for infusion vial
ARTG entry for	Medicine Registered	
Sponsor	Boehringer Ingelheim Pty Ltd	
Postal Address	PO Box 1969, NORTH RYDE, NSW, 2113 Australia	
ARTG Start Date	24/11/2023	
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 . SPEVIGO spesolimab (rch) 450 mg in 7.5 mL concentrated solution for infusion vial

Product Type	Single Medicine Product	Effective Date	15/04/2024
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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

SPEVIGO is indicated for the treatment of flares in adult patients with generalised pustular psoriasis.

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	Glass Type I Clear	30 Months	Store at 2 to 8 degrees Celsius	Neither child resistant closure nor restricted flow insert	Protect from Light Do not Freeze

Pack Size/Poison information

Pack Size	Poison Schedule
2 vials	(S4) Prescription Only Medicine

Components

1 . SPEVIGO spesolimab (rch) 450 mg in 7.5 mL concentrated solution for infusion vial

Dosage Form	Injection, intravenous infusion
Route of Administration	Intravenous Infusion
Visual Identification	Colourless to slightly brownish-yellow, clear to slightly opalescent solution

Active Ingredients

spesolimab	450 mg
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Other Ingredients (Excipients)

arginine hydrochloride
glacial acetic acid
polysorbate 20
sodium acetate trihydrate
sucrose
water for injections

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