



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	369935	VABYSMO faricimab 120 mg/mL solution for injection vial
ARTG entry for	Medicine Registered	
Sponsor	Roche Products Pty Ltd	
Postal Address	30-34 Hickson Road, Sydney, NSW, 2000 Australia	
ARTG Start Date	8/08/2022	
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 . VABYSMO faricimab 120 mg/mL solution for injection vial

Product Type	Single Medicine Product	Effective Date	19/02/2024
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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

Vabysmo is indicated for the treatment of:,- Neovascular (wet) age-related macular degeneration (nAMD),- Diabetic macular oedema (DMO).

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

Pack Size/Poison information

Pack Size	Poison Schedule
1 vial (commercial pack)	(S4) Prescription Only Medicine
1 vial (Physician's starter pack)	(S4) Prescription Only Medicine

Components

1 . VABYSMO faricimab 120 mg/mL solution for injection vial

Dosage Form	Injection, solution
Route of Administration	Intravitreal-Within The Vitreous Cavity Of The Eye
Visual Identification	A clear and slightly opalescent, colourless to brownish-yellow liquid, contained in a Type I colourless glass vial.

Active Ingredients

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faricimab

120 mg/mL

Other Ingredients (Excipients)

acetic acid

histidine

methionine

polysorbate 20

sodium chloride

sucrose

water for injections

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