Public Summary

Summary for ARTG Entry:	375304	BYOOVIZ ranibizumab 10 mg/mL solution for injection vial

ARTG entry for	Medicine Registered
Sponsor	Samsung Bioepis AU Pty Ltd
Postal Address	Level 16 / 201 Elizabeth Street, Sydney, NSW, 2000 Australia
ARTG Start Date	24/08/2022
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 . BYOOVIZ ranibizumab 10 mg/mL solution for injection vial

Product Type	Single Medicine Product	**Effective Date**	24/08/2022

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

Byooviz (ranibizumab) is indicated in adults for:,- the treatment of neovascular (wet) age-related macular degeneration (AMD),,- the treatment of visual impairment due to diabetic macular oedema (DME),,- treatment of proliferative diabetic retinopathy (PDR),,- the treatment of visual impairment due to choroidal neovascularisation (CNV),,- the treatment of visual impairment due to choroidal neovascularisation (CNV) secondary to pathologic myopia (PM),,- the treatment of visual impairment due to macular oedema secondary to retinal vein occlusion (RVO).

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

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	Refrigerate Protect from Light Do not Freeze

Pack Size/Poison information

Pack Size	Poison Schedule
1	(S4) Prescription Only Medicine

Components

1 . BYOOVIZ ranibizumab 10 mg/mL solution for injection vial

Dosage Form	Injection, solution
Route of Administration	Intravitreal-Within The Vitreous Cavity Of The Eye
Visual Identification	Vial: The solution is clear to slightly opalescent, colourless to pale yellow, sterile and preservative-free.

Active Ingredients

Ranibizumab	**2.3 mg**
Other Ingredients (Excipients)	
histidine hydrochloride monohydrate	
histidine	
polysorbate 20	
trehalose dihydrate	
water for injections	

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