




Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	381053	TAVNEOS avacopan 10 mg hard capsule bottle
ARTG entry for	Medicine Registered	
Sponsor	Seqirus Pty Ltd	
Postal Address	63 Poplar Road, PARKVILLE, VIC, 3052 Australia	
ARTG Start Date	31/01/2023	
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 . TAVNEOS avacopan 10 mg hard capsule bottle

Product Type	Single Medicine Product	Effective Date	19/03/2024
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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

Tavneos, in combination with a rituximab or cyclophosphamide based regimen, is indicated for the treatment of adults with anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA]).

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
Bottle	HDPE	3 Years	Store below 30 degrees Celsius	Child resistant closure	Store in Original Container Protect from Light

Pack Size/Poison information

Pack Size	Poison Schedule
180	(S4) Prescription Only Medicine
30	(S4) Prescription Only Medicine

Components

1 . TAVNEOS avacopan 10 mg hard capsule bottle

Dosage Form	Capsule, hard
Route of Administration	Oral
Visual Identification	Capsules with light orange cap and yellow body with CCX168 in black ink on the capsule.

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Active Ingredients

avacopan

10 mg

Other Ingredients (Excipients)

Gelatin

iron oxide black

iron oxide red

iron oxide yellow

macrogol 4000

PEG-40 hydrogenated castor oil

polysorbate 80

potassium hydroxide

Shellac

titanium dioxide

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