Public Summary

Summary for ARTG Entry:	378245	EVUSHELD tixagevimab 100mg/mL and cilgavimab 100mg/mL solution for injection in 150mg single dose vials

ARTG entry for	Medicine Registered (Provisional)
Sponsor	AstraZeneca Pty Ltd
Postal Address	PO Box 131, NORTH RYDE, NSW, 1670 Australia
ARTG Start Date	26/02/2022
Product Category	Medicine
Status	Active
Approval Area	Drug Safety Evaluation Branch

Medicine under additional monitoring

Conditions

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Conditions Applying to Therapeutic Goods Accepted for Registration or Listing as Goods Currently Supplied at the Commencement of the Therapeutic Goods Act 1989"

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 February 1992, other than condition No. 8 and condition No. 9.

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 February 1992, other than condition No. 11.

Except where the sponsor has been contracted by an overseas partry to manufacturer the goods and that party will be responsible for placing the goods on the market in countries other than Australia, the sponsor must have and shall retain, while the goods remain listed, evidence necessary to substantiate and support the accuracy of the indications in relation to the listed goods, and upon the request of the Head, Office of Prescription Medicines Authorisation Branch, Therapeutic Goods Administration, shall produce such evidence to this officer.

The conditions applying to these goods when they are exported from Australia are given below:

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, other than condition No. 8 and condition No. 9.

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, other than condition No.11

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.

The therapeutic goods grouped in this registration/listing as export only goods under the following names are included in the Australian Register of Therapeutic Goods and may not be supplied in Australia. Export Name(s) to be added:

Products

1 . EVUSHELD tixagevimab 100mg/mL and cilgavimab 100mg/mL solution for injection in 150mg single dose vials

Product Type	Composite Pack	**Effective Date**	20/09/2023

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

Provisionally Registered Indications

Pre-exposure prophylaxis,EVUSHELD (tixagevimab and cilgavimab) has provisional approval for the pre-exposure prophylaxis of COVID-19 in adults and adolescents aged 12 years and older weighing at least 40 kg,,- Who have moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments that make it likely that they will not mount an adequate immune response to COVID-19 vaccination or,- For whom vaccination with any approved COVID-19 vaccine is not recommended due to a history of severe adverse reaction (e.g., severe allergic reaction) to a

COVID-19 vaccine(s) and/or COVID-19 vaccine component(s).,See Section 4.2 Dose and method of administration and Section 5.2 Pharmacokinetic properties.,EVUSHELD is not recommended as a substitute for vaccination in individuals for whom COVID-19 vaccination is recommended.,This decision has been made on the basis of short-term efficacy and safety data. Continued approval depends on the evidence of longer-term efficacy and safety data from ongoing clinical trials.,Treatment,EVUSHELD has provisional approval for the treatment of adults with COVID-19, who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19. See Section 4.2 Dose and method of administration and Section 5.2 Pharmacokinetic properties.,This decision has been made on the basis of short-term efficacy and safety data. Continued approval depends on the evidence of longer-term efficacy and safety data from ongoing clinical trial.

Provisionally Registered Conditions

Extend the provisional registration period to 24 February 2026 for the provisionally registered indication as described in the letter dated 25 July 2023 from CESA, PMAB (PM-2023-02435-1-2) D23-2462281

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
Multiple containers	Glass Type I Clear	24 Months	Store at 2 to 8 degrees Celsius	Neither child resistant closure nor restricted flow insert	Protect from Light Do not Freeze Do not Shake

Pack Size/Poison information

Pack Size	Poison Schedule
1.5mL single-dose vials	(S4) Prescription Only Medicine

Components

1 . Cilgavimab

Dosage Form	Injection, solution
Route of Administration	Intramuscular
Visual Identification	Clear to opalescent, colourless to slightly yellow solution

Active Ingredients

cilgavimab	**150 mg**

Other Ingredients (Excipients)

histidine hydrochloride monohydrate
histidine
polysorbate 80
sucrose
water for injections

2 . Tixagevimab

Dosage Form	Injection, solution
Route of Administration	Intramuscular
Visual Identification	Clear to opalescent, colourless to slightly yellow solution

Active Ingredients

tixagevimab	**150 mg**

Other Ingredients (Excipients)

histidine hydrochloride monohydrate
histidine

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polysorbate 80

sucrose

water for injections

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