We wish to advise you of the following important updates to the EVUSHELD Product Information:

- **Recommended dosage has increased** from 300 mg to 600 mg for pre-exposure prophylaxis of COVID-19.[1]
- **6-monthly re-dosing option is available** for pre-exposure prophylaxis of COVID-19.[1]
- **Provisional approval for the treatment** of COVID-19.[1]

UPDATED DOSAGE RECOMMENDATION FOR PRE-EXPOSURE PROPHYLAXIS

The recommended initial dose of EVUSHELD has changed for pre-exposure prophylaxis from 300 mg (tixagevimab 150 mg/cilgavimab 150 mg) **to 600 mg** (tixagevimab 300 mg/cilgavimab 300 mg) administered as two separate 3.0 mL sequential IM injections at different injection sites, one in each of the gluteal muscles.[1]

Repeat doses of EVUSHELD 600 mg (tixagevimab 300 mg/cilgavimab 300 mg) is optional and may be given once every 6 months at the discretion of the treating healthcare professional.[1]

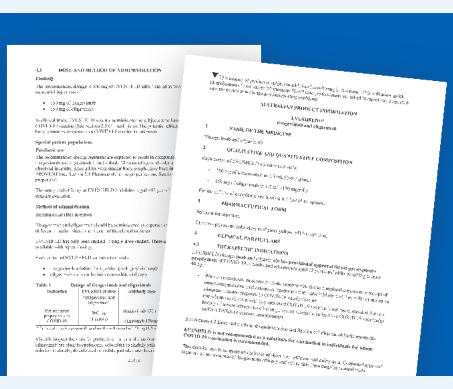
These updated dose recommendations are based on the totality of the available data including clinical pharmacology, pharmacokinetics, antiviral activity and clinical trial data.[1] The clinical safety of the 600 mg dose is supported by safety data in patients with mild-to-moderate COVID-19.[1]

EVUSHELD must be administered by a healthcare professional[1]

EVUSHELD 600 mg dose (2 cartons required; each carton contains 2 vials)[1]

tixagevimab 300 mg
2 vials needed
(dark grey cap)

cilgavimab 300 mg
2 vials needed
(white cap)



Download the EVUSHELD Product Information

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UPDATED INDICATION

EVUSHELD is now the **only** long-acting monoclonal antibody combination that has indications for both **prevention** and **treatment** of COVID-19.[1]

Pre-exposure prophylaxis indication

EVUSHELD 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:**[1]

- 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)

EVUSHELD is not recommended as a substitute for vaccination in individuals for whom COVID-19 vaccination is recommended.

Note: The safety and efficacy of EVUSHELD in children aged <18 years has not been established. No data are available.[1]

NEW

Treatment indication

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.[1]

Treatment dosage

Individuals being treated for COVID-19 should receive **EVUSHELD 600 mg** (tixagevimab 300 mg/cilgavimab 300 mg) as soon as possible after a positive viral test for SARS-CoV-2 and within 7 days after the onset of symptoms.[1]

HOW TO ACCESS EVUSHELD

AstraZeneca has agreements in place to supply the Australian Government with EVUSHELD via the National Medical Stockpile. Deployment of EVUSHELD will be managed by the Government and usage guidelines will be supported by the National COVID-19 Clinical Evidence Taskforce. Please also refer to any relevant guidelines published by your respective state or territory.

EVUSHELD™
tixagevimab, cilgavimab

AstraZeneca is committed to help end the global pandemic

PBS Information: This product is not listed on the PBS.

PLEASE CLICK HERE TO REVIEW FULL PRODUCT INFORMATION BEFORE PRESCRIBING. FURTHER INFORMATION AVAILABLE ON REQUEST FROM ASTRAZENECA ON 1800 805 342 OR www.astrazeneca.com.au/PI

IM = intramuscular.

Reference: 1. EVUSHELD (tixagevimab and cilgavimab) Australian Product Information.

Registered user AstraZeneca Pty. Ltd. ABN 54 009 682 311. 66 Talavera Road, Macquarie Park, NSW 2113. www.astrazeneca.com.au. For Medical Information enquiries or to report an adverse event or product quality complaint: Telephone 1800 805 342 or via https://contactazmedical.astrazeneca.com or email Medical Information enquiries to medinfo.australia@astrazeneca.com.

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AstraZeneca