



Australian Government

Department of Health
and Aged Care

BE COVIDSAFE

Use of Evusheld

Updated February 2023

Evusheld® (tixagevimab and cilgavimab) by AstraZeneca Pty Ltd was the first non-vaccine medication in Australia for the prevention of COVID-19 in people who are at risk of infection but have not been exposed to the virus. This is known as pre-exposure prophylaxis (PrEP) of COVID-19.

It was provisionally approved by the Therapeutic Goods Administration (TGA) on 24 February 2022 as an intra-muscular (IM) injection for the prevention (pre-exposure prophylaxis) of COVID-19 in people aged 12 years and older weighing at least 40kg with sub-optimal or no protection from COVID-19 vaccines.

On 12 December 2022, the TGA amended the conditions of its provisional approval for the use of Evusheld for PrEP in individuals 12 years and over, increasing the required dosage regime from 150-150mg to 300-300mg dose with the option to provide repeat dosing every six months.

Evusheld also received provisional approval as a treatment for adults with COVID-19, who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19.

Evusheld is not recommended as a substitute for COVID-19 vaccination.

The drug must be prescribed by an authorised prescriber, who has assessed the suitability of this medication, prior to administration to an individual.

Prescribers should take into consideration what is known about the characteristics of the circulating viral variants, including geographical prevalence and local guidelines when prescribing Evusheld.

Who is the medicine for?

Evusheld is prioritised for those who are at highest risk of disease progression and likely to derive the most benefit. This includes PrEP in severely immunocompromised individuals not expected to mount an adequate immune response to COVID-19 vaccination (e.g. due to underlying medical conditions or treatments that compromise the body's immune system).

The use of Evusheld as a treatment should prioritise adults with COVID-19, who are at increased risk of progressing to severe COVID-19. There are alternative COVID-19 antivirals that can be considered for treatment of such patients, e.g. the Pharmaceutical Benefits Scheme (PBS) listed oral antivirals Paxlovid® (nirmatrelvir + ritonavir) and Lagevrio® (molnupiravir). The intravenous antiviral Veklury® (remdesivir) can also be considered for use in adults and paediatric patients for the treatment of COVID-19.

Clinical particulars

Side effects

For side effects and precautions for use please refer to the TGA [product information sheet on Evusheld](#).

Interactions

Tixagevimab and cilgavimab (Evusheld) are not renally excreted or metabolized by cytochrome P450 (CYP) enzymes; therefore, interactions with concomitant medications that are renally excreted or that are substrates, inducers, or inhibitors of CYP enzymes are unlikely.

Dosing

The dosage of Evusheld for PrEP and treatment is 300mg of tixagevimab and 300mg of cilgavimab administered as four separate sequential IM injections, two in each of the gluteal muscles.

Repeat 300-300mg dosing for PrEP is optional every six months.

See the [TGA website](#) for access to the consumer medicine information summary and product information for clinical and healthcare details.

No dosage adjustment is recommended in pregnant or lactating individuals, in geriatrics, and in individuals with renal impairment. Evusheld should only be used during pregnancy if the potential benefit outweighs the potential risk for the mother and the foetus.

Antiviral resistance

Patients who receive Evusheld prophylactically should be informed of the potential for breakthrough infections to occur due to the development of viral variants that are resistant to tixagevimab and cilgavimab. Some of the viral variants likely to be resistant to tixagevimab and cilgavimab are in widespread circulation in Australia as of early February 2023.

Patients given Evusheld for PrEP should discuss in advance with their healthcare provider eligibility and suitability for (other) antiviral treatments, and how to access the preferred one of these treatments early, in the event of breakthrough COVID-19 infection.

Patients should seek medical advice if signs or symptoms of COVID-19 occur (the most common symptoms include fever, cough, tiredness and loss of taste or smell; the most serious symptoms include difficulty breathing or shortness of breath, loss of speech or mobility, or confusion and chest pain).

As noted above, use of Evusheld for treatment should also take into account the circulation of viral variants likely to be resistant to the two antibodies in Evusheld.

Additional information is provided in the [Product Information](#).

Accessing this medication

Evusheld is a prescription only (S4) medicine which requires a prescription from an authorised prescriber.

The Australian Government, through the [National Medical Stockpile \(NMS\)](#), has deployed supplies of Evusheld to all state and territory health departments for supply to high priority groups. Each state and territory is responsible for the distribution of this supply within their jurisdiction following their COVID-19 care arrangements.

To access supplies of Evusheld, healthcare professionals should contact their relevant state or territory health department. Access to Evusheld may differ between jurisdictions.

Evusheld is not currently listed on the Pharmaceutical Benefits Scheme, for either PrEP or treatment.

Medicine administration

Supply of the medications can be used in a manner consistent with medicine regulation in your jurisdiction.

Evusheld is supplied as a co-packaged carton containing two vials, noting two packages are required for one dose:

- one single-dose vial of tixagevimab injection as a sterile, preservative-free, clear to opalescent and colourless to slightly yellow solution.
- one single-dose vial of cilgavimab injection as a sterile, preservative-free, clear to opalescent and colourless to slightly yellow solution.

Store unopened vials in a refrigerator at 2°C to 8°C in the original carton to protect from light.

Discard any unused portion. DO NOT FREEZE. DO NOT SHAKE.

Please review the [TGA Evusheld product information](#) and ensure that this medication is administered safely.

Adverse events

Please ensure that all possible adverse reactions are reported using the usual existing mechanisms. Anyone can report an adverse event.

To report an event online you will need the following information:

- reporter details
- patient details
- medicine details
- reaction details

See the [TGA Adverse Event Management System privacy statement](#).