Fact Sheet

OFFICIAL

Tixagevimab and Cilgavimab (Evusheld®)

Information for Prescribers and Health Professionals

A limited supply of tixagevimab and cilgavimab (Evusheld®) from the National Medical Stockpile (NMS) is available in South Australia, for use in high-risk people for pre-exposure prophylaxis of COVID-19. See the SA Health COVID-19: Pre-Exposure Prophylaxis (PrEP) with Tixagevimab plus Cilgavimab Clinical Guideline and Product Information for further information.

What is the benefit of tixagevimab and cilgavimab (Evusheld®)?

Tixagevimab and cilgavimab (Evusheld®) are monoclonal antibodies designed to block viral attachment and entry into cells. A large ongoing Phase III, randomised, double-blind placebo-controlled clinical trial (PROVENT) in high-risk individuals showed an 83% reduction of symptomatic COVID-19 in the six months after administration. Please see the Australian guidelines for the clinical care of people with COVID-19 for further details about the benefits of tixagevimab and cilgavimab (Evusheld®) as a pre-exposure prophylactic treatment for individuals at risk of severe disease from COVID-19.

What patients can receive tixagevimab and cilgavimab (Evusheld®)?

Patients who may benefit from tixagevimab and cilgavimab (Evusheld®) include those with moderate to severe immune compromise that make it likely that they will not mount an adequate immune response to a COVID-19 vaccination, or for whom vaccination is not recommended due to a history of severe adverse reaction to a COVID-19 vaccine/vaccine components.

Current eligibility in South Australia is available at SA Health's COVID-19 treatments and referrals website. Eligibility has been restricted in the first instance due to limited supply from the National Medical Stockpile. Eligibility criteria will be expanded as additional supply becomes available. Updates will be communicated to health services and updated at the webpage above.

How is tixagevimab and cilgavimab (Evusheld®) given?

Tixagevimab and cilgavimab (Evusheld®) is administered as two intramuscular injections (gluteal).

What is the recommended observation time for a patient after receiving tixagevimab and cilgavimab (Evusheld®)?

Currently, a minimum 15-minute observation time is recommended.

In the PROVENT clinical trial, observation time post administration of tixagevimab and cilgavimab (Evusheld®) was 60 minutes. There were no anaphylactic reactions to the medication after 15 minutes in the PROVENT trial. Observation time should balance individual patient risk of a reaction with risk of the patient being exposed to COVID-19 or other viruses in the time spent in an indoor environment with other people.

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Is it necessary or desirable to check antibody status prior to administration?

Serology testing is not required prior to administration of tixagevimab and cilgavimab (Evusheld®).

Is the timing between a patient receiving a COVID-19 vaccine and being administered tixagevimab and cilgavimab (Evusheld®) significant?

If the patient has recently received a COVID-19 vaccine, a period of at least two weeks from the date of that vaccination to administer tixagevimab and cilgavimab (Evusheld®) is advised.

Is the timing between a patient having a confirmed COVID-19 infection and being administered tixagevimab and cilgavimab (Evusheld®) significant?

If the patient recently had a confirmed COVID-19 infection, it is suggested to wait 30 days from the start of the infection before administering tixagevimab and cilgavimab (Evusheld®). In some instances it can be given within 30 days on the advice of a specialist.

Are patients required to obtain a negative PCR prior to receiving tixagevimab and cilgavimab (Evusheld®)?

A negative RAT or PCR is recommended prior to administration, as treatment with antivirals may be indicated if the patient returns a positive result. Some health care settings may require patients to have a negative RAT or PCR prior to entry.

What are the implications of a patient having a past history of receiving COVID-19 medications such as antivirals?

Tixagevimab and cilgavimab (Evusheld®) can still be given if a person has previously had antivirals for the treatment of COVID-19. If the patient has had a previous COVID-19 infection which required treatment, it is suggested to wait 30 days from the start of the infection before administering tixagevimab and cilgavimab (Evusheld®).

Are there any restrictions in the co-administration of tixagevimab and cilgavimab (Evusheld®) with the administration of B cell depleting therapies?

There are no current restrictions on timing of doses of tixagevimab and cilgavimab (Evusheld®) relative to timing of other immunosuppressive therapies, including B cell depleting therapies.

Tixagevimab and cilgavimab (Evusheld®) in people with cardiovascular disease

In the PROVENT clinical trial, there was a higher rate of cardiac serious adverse events (SAEs), including myocardial infarction (one fatal SAE) and cardiac failure, in subjects who received tixagevimab and cilgavimab (Evusheld®) compared to placebo.

All subjects who experienced cardiac SAEs had cardiovascular risk factors and/or a prior history of cardiovascular disease. In PROVENT, there was a higher rate of thromboembolic serious adverse events in subjects who received tixagevimab and cilgavimab (Evusheld®), compared to placebo.

One event of mesenteric artery thrombosis was reported as a SAE, 6 days after injection in a subject without a known medical history of coagulation disorders. A CT scan of the abdomen and pelvis at the time of the event showed atheromatous overload of vascular vessels. A possible relationship with tixagevimab and cilgavimab (Evusheld®) cannot be ruled out.

A causal relationship between tixagevimab and cilgavimab (Evusheld®) and these events has not been established.

Consider the risks and benefits prior to initiating tixagevimab and cilgavimab (Evusheld®) in individuals at high risk for cardiovascular events, and advise individuals to seek immediate medical attention if they experience any signs or symptoms suggestive of a cardiovascular event.

What is the current recommended dose of tixagevimab and cilgavimab (Evusheld®)?

The approved dose for pre-exposure prophylaxis is 150 mg of tixagevimab and 150 mg of cilgavimab administered as separate sequential IM injections. See the product information for further information.

It is noted that information regarding consideration of a higher Evusheld® dose is under review by the Therapeutic Goods Administration (TGA).

Can tixagevimab and cilgavimab (Evusheld®) be given intravenously?

Clinically significant bleeding disorders, such as thrombocytopenia and other coagulation disorders, are a precaution for intramuscular injections. For patients at high risk of bleeding, administration via an intravenous route may be an option. Seek specialist advice from a major health service regarding this.

Are there any medication related interactions with tixagevimab and cilgavimab (Evusheld®)?

Drug-drug interaction studies have not been performed. However, 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 and can be co-administered. The University of Liverpool COVID-19 Drug Interactions checker provides an interactive tool for COVID-19 therapies and is a recommend resource for updates.

Is tixagevimab and cilgavimab (Evusheld®) being used in Paediatric populations?

As the risk of severe COVID-19 is lower in children, tixagevimab and cilgavimab (Evusheld®) is recommended to only be used in high-risk children who have significant immunosuppression in addition to another risk factor for severe disease. This should be discussed with a paediatric infectious diseases specialist and immunologist. Please see the Product Information which outlines a summary of advice regarding administration of tixagevimab and cilgavimab (Evusheld®) in paediatric cohorts. As per the Product Information, the recommended dosing regimens are expected to result in comparable serum exposures of tixagevimab and cilgavimab (Evusheld®) in individuals 12 years of age and older and weighing at least 40 kg as observed in adults. The safety and efficacy of tixagevimab and cilgavimab (Evusheld®) in children aged under 12 and less than 40 kg is still being investigated.

What models of care are currently being used to deliver tixagevimab and cilgavimab (Evusheld®) to eligible cohorts?

Inpatient and outpatient models of care are being used currently to deliver Evusheld®, in both public hospitals and some private hospitals. This includes an opportunistic approach where patients are being offered treatment as part of a routine outpatient appointment or during an inpatient admission.

Additional alternative pathways, such as specific outpatient clinics, are also being developed to improve access and prescribing pathways for eligible people.

How is the data going to be managed?

Health services administering tixagevimab and cilgavimab (Evusheld®) will be responsible for patient record documentation as per standard process for all clinical treatment. Limited, de-identified patient information is collected as part of the request to access process which allows the department to monitor stock use and informs reporting obligations back to the Commonwealth. As per the Product Information, healthcare professionals should report any suspected adverse reactions at www.tga.gov.au/reporting-problems.

Acknowledgement : Some content has been adapted from the Victorian Department of Health - Pre-exposure prophylactic treatment for COVID-19: tixagevimab and cilgavimab (Evusheld™) – Frequently asked questions.

For more information

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