Queensland Government

Tixagevimab plus cilgavimab (Evusheld®)

Adult (18 years and over) and
Young Person (12–17 years)
Informed consent: patient information

(Affix identification label here)

URN:

Family name:

Given name(s):

Address:

Date of birth: Sex: ☐ M ☐ F ☐ I

A copy of this patient information sheet should be given to the patient/substitute decision-maker/parent/legal guardian/ other person* to read carefully and allow time to ask any questions about the treatment. A copy should be included in the patient's medical record.

What is Evusheld® and how will it help me (or my child)?

This medicine contains two drugs, tixagevimab (TICKS-a-GEV-ee-mab) and cilgavimab (sill-GAV-ee-mab), which are given at the same time to prevent or treat COVID-19 infection in people who are at high risk. These two drugs are co-packaged under the brand name Evusheld® (EV-u-sheld).

The drugs are long-acting monoclonal antibodies that bind to the COVID-19 spike protein and stop it from interacting with human cells, thereby preventing COVID-19 infection from occurring.

Evusheld® has been granted provisional approval in Australia by the Therapeutic Goods Administration (TGA) for use in people aged 12 years and older (and who weigh at least 40kg), if:

- you are moderately to severely immunocompromised due to a medical condition or treatment (i.e. you may not get full benefit from the COVID-19 vaccination); or
- vaccination is not recommended (i.e. due to a history of severe adverse reaction to a COVID-19 vaccine or COVID-19 vaccine component).

This patient information was developed using the National COVID-19 Clinical Evidence Taskforce guidelines and the PROVENT[1] and TACKLE[2] trials.

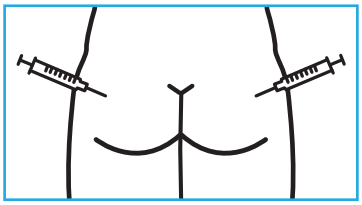

Image: Intramuscular injections in buttock. ID: 1293634708 (adapted). www.shutterstock.com

Preparing for the treatment

A doctor/clinician will discuss the risks and benefits of treatment with you and must obtain consent before it is given. The doctor/clinician will need to know about:

- any allergies
- any heart problems
- any blood clotting issues (e.g. if you have any blood disorders or low platelets or take a blood thinner)
- whether you are pregnant or breastfeeding or planning a pregnancy
- any other medical conditions and all your current medications (including medications or supplements you take without a prescription)
- timing of any COVID-19 vaccines.

Because Evusheld® is a new product, information about how well it works and its safety is still being monitored. It is important that you understand when and why Evusheld® may be useful. Your doctor/clinician will discuss with you about how well it works and how safe it is in your condition.

How is Evusheld® given to me (or my child)?

Evusheld® is usually given as two intramuscular (IM) injections. An injection of tixagevimab goes into one buttock and an injection of cilgavimab goes into the other buttock.

You (or your child) need to be monitored for 15 minutes after the injections just to be sure you do not have any immediate side effects.

What are the risks of being given Evusheld®?

All medicines can have side effects. Sometimes they are serious, but most of the time they are not. As mentioned above, this is a new medication and information about side effects will continue to be reviewed.

Possible side effects of Evusheld®

Speak to your doctor/clinician if you have any of these side effects and they worry you or don't get better:

- pain
- bruising
- swelling at the site of injection.

Call your doctor/clinician or an ambulance (000) straight away if you have any of these side effects:

- heart problems or blood clots (report any of the following signs/symptoms which could be caused by heart problems or blood clots):
  - pain, pressure, or discomfort in the chest, arms, neck, back, stomach, legs or jaw
  - abdominal pain
  - shortness of breath
  - faster than normal heart beat
  - feeling tired or weak (fatigue)

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- feeling sick (nausea)
- swelling in your ankles or lower legs
- coughing up blood
- difficulty speaking or confusion
- loss of movement or weakness on one side of the body or face
- severe headache.

Immediately tell the doctor/clinician or nurse if these symptoms occur:

- allergic reactions (anaphylaxis), including:
  - feeling short of breath, wheezing, difficulty breathing
  - swelling of the face, lips, tongue or other parts of the body
  - severe skin rash including itching and hives.

If the person has already left the healthcare facility, call an ambulance and immediately go to the nearest hospital.

The evidence for using Evusheld® to prevent COVID-19 infection comes from the PROVENT trial[1]. Overall, 35% of people who received Evusheld® in the PROVENT trial reported a side effect, as did 34% of people who received placebo (an inactive substance). Serious side effects were very rare (only 1% of participants). The most common side effects of Evusheld® were headaches (occurred in 6% of people in the trial) and fatigue (occurred in 4% of people in the trial).

There was a small increased risk of heart problems with of Evusheld® (occurred in 0.6% of people) compared to the people that did not receive this treatment (occurred in 0.2% of people). However, it is not clear from the trial whether Evusheld® was causing these side effects.

It is possible that other unknown side effects may occur with Evusheld®. Any side effects or symptoms at all should be reported to the doctor/clinician directly. Your doctor/clinician will report the details of the reaction to the TGA and document this in your medical record.

What are the risks of not having Evusheld®?

Evusheld® is used to prevent or to treat COVID-19 infection. If you get exposed to the virus, these medications work to stop it from becoming an infection. If getting COVID-19 would put you at high risk of having a serious outcome (i.e. needing to go to hospital or getting very sick) this medication aims to protect you.

The evidence for this treatment comes from the PROVENT trial[1], where 3,441 people received Evusheld® and 1,731 people received a placebo (an inactive substance). Of the people who received Evusheld® 8 people (0.2%) went on to develop COVID-19 with symptoms, compared to 17 people (1%) who were given a placebo.

The TACKLE trial showed that people who had mild or moderate COVID-19 infection were less likely to develop severe COVID-19 or to die if they received Evusheld®, compared to receiving a placebo[2].

Are there alternative treatments?

Vaccination provides the best protection against COVID-19 infection. Evusheld® is not a substitute for vaccination in people who are recommended to receive COVID-19 vaccine.

Vaccines are not medications. Talk to your doctor/clinician to see if your circumstances mean there are other medicines for treatment or prevention of COVID-19 to consider.

What should I (or my child) expect after treatment?

Delayed reactions are rare but can still happen, so it is important that anyone who receives Evusheld® watches carefully for any side effects. Any concerns should be reported to the doctor or nurse immediately.

These drugs are long-acting and are expected to provide 6 months of protection after administration. Because Evusheld® is a new treatment, there is no information about safety or effectiveness of repeat doses. At this stage, Evusheld® is only approved as a single dose. Sometimes your doctor/clinician might suggest a second dose after six months, this may be considered off-label use.

Some patients may still develop COVID-19 after Evusheld® and it may be severe. It is important that you follow usual health advice about COVID-19 and test and isolate if you develop symptoms. The most common symptoms of COVID-19 are fever, cough, sore throat, headache, nausea, vomiting or diarrhoea and loss of taste or smell. If you start to feel unwell – call 13 HEALTH (13 43 25 84). If you have serious symptoms, like difficulty breathing – call 000 and ask for an ambulance.

When can I (or my child) get vaccinated?

Vaccination does not need to be delayed after being given Evusheld®, this means you can get a vaccine any time after being given Evusheld®. However, if you have recently had a COVID-19 vaccine, Evusheld® should not be given within 2 weeks of your vaccination to give your body time for the vaccine to start working.

Evusheld® may reduce your body's immune response to a COVID-19 vaccine.

Is there any impact on fertility, pregnancy and breastfeeding?

There are no data currently available regarding the effects of Evusheld® on fertility in humans.

Due to the lack of information about Evusheld® in pregnancy and breastfeeding, it is generally not recommended for patients who are pregnant or breastfeeding, unless in exceptional circumstances with specialist involvement.

Where can I find support or more information?

- For information on testing and what to do if you think you may have COVID-19. Symptoms of coronavirus (COVID-19) | Health and wellbeing | Queensland Government (www.qld.gov.au).
- If you start to feel unwell but your symptoms are not serious – **call 13 HEALTH (13 43 25 84)**.
- If you have serious symptoms, like difficulty breathing – **call 000 and ask for an ambulance**.
- Medication for treating COVID-19. Health Direct – Free Australian health advice you can count on. www.healthdirect.gov.au/covid-19-medication.
- National COVID-19 Clinical Evidence Taskforce. Australian Guidelines for the Clinical Care of people with COVID-19. https://covid19evidence.net.au/#living-guidelines.
- Consumer Medicine Information: Evusheld (https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2022-CMI-01157-1&d=20220419172310101).
- Intramuscular AZD7442 (Tixagevimab–Cilgavimab) for Prevention of Covid-19 (PROVENT trial) published in the *New England Journal of Medicine* www.nejm.org/doi/full/10.1056/NEJMoa2116620.

References:

1. Levin, M, Ustianowski A, De Wit S, et al. LB5. PROVENT: Phase 3 Study of Efficacy and Safety of AZD7442 (Tixagevimab/Cilgavimab) for Pre-exposure Prophylaxis of COVID-19 in Adults. Open Forum Infect Dis. 2021 Nov; 8(Suppl 1): S810.
2. Efficacy and safety of intramuscular administration of tixagevimab–cilgavimab for early outpatient treatment of COVID-19 (TACKLE): a phase 3, randomised, double-blind, placebo-controlled trial published in The Lancet Respiratory Medicine. www.thelancet.com/journals/lanres/article/PIIS2213-2600(22)00180-1/fulltext

*Formal arrangements, such as parenting/custody orders, adoption, or other formally recognised carer/guardianship arrangements. Refer to the Queensland Health 'Guide to Informed Decision-making in Health Care' and local policy and procedures. Complete the source of decision-making authority as applicable.