

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your healthcare provider.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using EVUSHELD?

EVUSHELD contains the active ingredients tixagevimab and cilgavimab. EVUSHELD is used to:

- help prevent adults and adolescents (aged 12 years and older weighing at least 40 kg), who have not been recently in contact with someone who has COVID-19, from getting COVID-19 illness when they are unlikely to be protected by a COVID-19 vaccine or when vaccination is not recommended.
- treat adults with COVID-19 who do not require supplemental oxygen to treat COVID-19 and who are at increased risk for the illness becoming severe based on the evaluation of your doctor.

For more information, see Section [1. Why am I using EVUSHELD?](#) in the full CMI.

2. What should I know before I use EVUSHELD?

You must not be given EVUSHELD if you have ever had an allergic reaction to tixagevimab and cilgavimab or any of the ingredients listed at the end of the CMI.

Check with your doctor if you have any low numbers of blood platelets (which help blood clotting), have a bleeding disorder or are taking a blood thinning medicine (to prevent blood clots).

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use EVUSHELD?](#) in the full CMI.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

For more information, see Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is EVUSHELD given?

- EVUSHELD will be given to you by your healthcare provider as two intramuscular injections, one into each of your buttocks.

More instructions can be found in Section [4. How is EVUSHELD given?](#) in the full CMI.

5. What should I know while I am being given EVUSHELD?

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| Things you should do | <ul style="list-style-type: none">• Seek medical attention if you think you experience any problems with this medicine.• Remind any healthcare provider you visit that you are using EVUSHELD.• If you are taking EVUSHELD to help prevent you from getting COVID-19, and you get symptoms of COVID-19 please contact your doctor right away. |
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For more information, see Section [5. What should I know while using EVUSHELD?](#) in the full CMI.

6. Are there any side effects?

Pain, bruising of the skin, soreness or swelling, at the injection site are common side effects.

Serious allergic reactions. They may include the following symptoms: difficulty breathing or swallowing, swelling of the face, lips, tongue or throat, severe itching of the skin, with a red rash or raised bumps.

Serious cardiac and blood clot adverse events including the following symptoms: 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), feeling sick (nausea), swelling in your ankles or lower legs, coughing up blood, difficulties speaking or confusion, loss of movement or weakness on one side of the body or face, severe headache. It is not known if these events are related to EVUSHELD or underlying medical conditions.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

- ▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

EVUSHELD™

Active ingredients: tixagevimab and cilgavimab

EVUSHELD has **provisional approval** to:

- help prevent adults and adolescents (aged 12 years and older weighing at least 40 kg), who have not been recently in contact with someone who has COVID-19, from getting COVID-19 illness when they:
- have an illness or take medicines making them unlikely to respond to or be protected by vaccination against COVID- 9
- or are not recommended to have a vaccine due to a history of severe allergies to a COVID-19 vaccine or its components.

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

- treat adults with COVID-19 who do not require supplemental oxygen to treat COVID-19 and who are at increased risk for the illness becoming severe based on the evaluation of your doctor.

This approval has been granted on the basis of short term efficacy and safety data. Evidence of longer term efficacy and safety from ongoing trial continues to be gathered and assessed.

Consumer Medicine Information (CMI)

This leaflet provides important information about using EVUSHELD. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using EVUSHELD.**

Where to find information in this leaflet:

- [1. Why am I using EVUSHELD?](#)
- [2. What should I know before I use EVUSHELD?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is EVUSHELD given?](#)
- [5. What should I know while I am being given EVUSHELD?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using EVUSHELD?

EVUSHELD contains the active ingredients **tixagevimab and cilgavimab**.

Tixagevimab and cilgavimab are types of protein called 'monoclonal antibodies'.

Tixagevimab and cilgavimab (EVUSHELD) work specifically against the SARS-CoV-2 virus preventing it from entering your cells. This can help prevent you from getting COVID-19 illness or help your body to overcome the infection and reduce the risk of you developing severe illness.

COVID-19 is an illness which can affect your lungs, airways and other organs. COVID-19 illnesses can be very mild (sometimes with no symptoms), however in some cases symptoms can be severe and can result in hospitalisation or even death.

What EVUSHELD is used for

EVUSHELD is used to help prevent adults and adolescents (aged 12 years and older weighing at least 40 kg), who have not been recently in contact with someone who has COVID-19, from getting COVID-19 illness when they:

- have an illness or take medicines making them unlikely to respond to or be protected by vaccination against COVID-19

- or are not recommended to have a vaccine due to a history of severe allergies to a COVID-19 vaccine or its components.

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

EVUSHELD is also used to treat adults with COVID-19 who do not require supplemental oxygen to treat COVID-19 and who are at increased risk for the illness becoming severe based on the evaluation of your doctor.

2. What should I know before I use EVUSHELD?

Warnings

Do not use EVUSHELD if:

- you are allergic to tixagevimab, cilgavimab or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- Have any allergies
- have any low numbers of blood platelets (which help blood clotting)
- have had a heart attack or stroke, have other heart problems, or are at high-risk of cardiac (heart) events
- have a bleeding disorder or are taking a blood thinning medicine (to prevent blood clots)
- are taking, have recently taken or might take any medicines for any other condition.

If you have received a COVID-19 vaccine, tell your doctor or nurse, prior to using EVUSHELD. It is possible that EVUSHELD may reduce your body's immune response to a COVID-19 vaccine.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your healthcare provider for advice before receiving this medicine.

Tell your doctor if you are pregnant, or if you might be pregnant. There is not enough information to be sure that this medicine is safe for use in pregnancy. EVUSHELD will only be given if the potential benefits of treatment outweighs the potential risks to the mother and the unborn child.

Talk to your doctor if you are breastfeeding. It is not yet known whether EVUSHELD passes into human milk or what the effects might be on the baby or milk production. Your doctor will help you decide whether to keep breastfeeding or to start treatment with this medicine.

Children and adolescents

- EVUSHELD should not be given to children below 12 years of age or weighing less than 40 kg.

3. What if I am taking other medicines?

If you are getting a COVID-19 vaccine, tell your doctor, nurse or pharmacist that you have used or are using EVUSHELD.

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect EVUSHELD.

4. How is EVUSHELD given?

How much EVUSHELD is given

EVUSHELD consists of two medicines, tixagevimab and cilgavimab. You will receive 2 injections one after the other.

The recommended dose is 600 mg given as two 3 mL injections:

- 300 mg of tixagevimab
- 300 mg of cilgavimab.

You may also receive repeat doses of 600 mg EVUSHELD (300 mg of tixagevimab and 300 mg of cilgavimab) every 6 months for the continuous prevention of COVID-19, as advised by your doctor.

How you will be given EVUSHELD

- EVUSHELD will be given to you in a healthcare facility under the supervision of a healthcare professional who is experienced in the use of this type of treatment. They will watch you closely while you are being given this medicine. This is in case you get any side effects.
- EVUSHELD will be given to you by your healthcare provider as two intramuscular injections, one into each of your buttocks.
- Your doctor or nurse will decide how long you will be monitored after you are given the medicine, in case you have any side effects.

If you use too much EVUSHELD

As EVUSHELD is given under the close supervision of a healthcare provider it is unlikely that you will be given too much.

If you are concerned that you have been given too much EVUSHELD, tell your healthcare provider immediately, phone the Poisons Information Centre (by calling 13 11 26) or go to the Emergency Department at your nearest hospital

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while I am being given EVUSHELD?

Things you should do

Tell any other doctors you see that you have had this medicine to prevent or treat COVID-19.

If you are getting a COVID-19 vaccine, tell the doctor, nurse or pharmacist you have had this medicine.

COVID-19 is caused by different strains (variants) of the SARS-CoV-2 virus that change over time. EVUSHELD may be less effective at preventing COVID-19 caused by some strains than others. If you are taking EVUSHELD to help prevent you from getting COVID-19, and you get symptoms of COVID-19 please contact your doctor right away. COVID-19 affects different people in different ways:

- 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.

Call your doctor straight away if you notice any signs of serious allergic reaction, such as:

- difficulty breathing or swallowing
- swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bumps.

Driving or using machines

It is unlikely that EVUSHELD will affect your ability to drive or use machines.

Looking after your medicine

EVUSHELD will be given to you in a healthcare facility and the healthcare professionals caring for you will be responsible for storing this medicine.

Unopened vials should be stored in a refrigerator (at 2°C to 8°C), in the original carton to protect from light.

- Do not freeze. Do not shake.
- Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Prepared syringes should be used immediately. If necessary, store the prepared syringes for no more than 4 hours either:

- at 2°C to 8°C, or
- at room temperature up to 25°C

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

- Unused medicine or waste material will be discarded by your healthcare professional.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Allergic reactions may be serious and have occurred during or following administration of EVUSHELD (see [5. What should I know while using EVUSHELD?](#) and serious side effects table below).

Cardiac (heart) and blood clot events: serious cardiac and blood clot adverse events have happened, but were not common in clinical trials. In the clinical trial studying preexposure prophylaxis for the prevention of COVID-19, in people with risk factors for cardiac events (including a history of heart attack), more people who received EVUSHELD experienced serious cardiac events than people who did not receive EVUSHELD. More people who received EVUSHELD experienced blood clot events than people who did not receive EVUSHELD. One event of blood clot in a major blood vessel was reported 6 days after EVUSHELD was given to an individual. The CT scan of the abdominal and groin region at the time of the event showed pre-existing deposits in the blood vessels. A possible relationship between this event and the treatment with EVUSHELD cannot be ruled out. Overall, it is not known if these cardiac and blood clot events are related to EVUSHELD or underlying medical conditions.

Contact your healthcare provider or get medical help right away if you get any symptoms of cardiac events, including pain, pressure, or discomfort in the chest, arms, neck, back, stomach or jaw, as well as shortness of breath, feeling tired or weak (fatigue), feeling sick (nausea), or swelling in your ankles or lower legs.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

| Less serious side effects | What to do |
|--|---|
| Skin: <ul style="list-style-type: none"> Pain, bruising of the skin, soreness or swelling at the injection site. | Speak to your doctor if you have any of these side effects and they worry you. |

Serious side effects

| Serious side effects | What to do |
|--|---|
| Serious allergic reactions, some of the symptoms may include: <ul style="list-style-type: none"> Difficulty breathing or swallowing Swelling of the face, lips, tongue or throat Severe itching of the skin, with a red rash or raised bumps. Cardiac (heart) and blood clot events: <ul style="list-style-type: none"> 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), feeling sick (nausea), swelling in your ankles or lower legs, coughing up blood, difficulties speaking or confusion, loss of movement or | Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects. |

| Serious side effects | What to do |
|--|------------|
| weakness on one side of the body or face, severe headache. | |

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What EVUSHELD contains

| | |
|---|---|
| Active ingredient (main ingredient) | tixagevimab and cilgavimab |
| Other ingredients (inactive ingredients) | histidine, histidine hydrochloride monohydrate, sucrose, polysorbate#80 and water for injection |

You should not be given this medicine if you are allergic to any of these ingredients.

What EVUSHELD looks like

Each carton of EVUSHELD contains:

- one single use clear glass vial of tixagevimab solution for injection (dark grey vial cap)
- one single use clear glass vial of cilgavimab solution for injection (white vial cap).

Each of the single use vials contains a clear to opalescent, colourless to slightly yellow solution.

Aust R 378245

Who distributes EVUSHELD

AstraZeneca Pty Ltd
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 66 Talavera Road
 MACQUARIE PARK NSW 2113
 Telephone: 1800 805 342

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