Information about the COVID-19 Evusheld Monoclonal Antibody Treatment

Disclaimer: as of January 26, 2023, the U.S. Food and Drug Administration has revoked approval of AstraZeneca's long-acting monoclonal antibody (mAb) cocktail called Evusheld in all U.S. states and territories. This is due to an increase in COVID-19 cases caused by Omicron sub-variants and data showing that Evusheld is unlikely to be as effective against them.[1] It was first made available for emergency use for pre-exposure prophylaxis (prevention) of COVID-19 in certain adult and pediatric individuals on December 8, 2021.[2,3]

Like many other viruses, the SARS-CoV-2 virus that causes COVID-19 is evolving and changing over time. As COVID-19 becomes an endemic disease, meaning that it is still present but not causing significant disruption in our daily lives, the virus will continue to change and new variants will arise.

In the future, new variants may arise that may once again be prevented with Evusheld. This fact sheet contains information about the Evusheld treatment to help you make informed decisions about pre-exposure prophylaxis for COVID-19 that may help reduce your risk of infection and severe illness.

How does Evusheld work?

Evusheld provides your immune system with two different long-acting antibodies to protect you from COVID-19. The antibodies are specifically directed against the SARS-CoV2 virus and block it from attaching to and entering the cells in your body. The treatment is given to you before you are exposed to or test positive for COVID-19.[2]

Who is Evusheld for?

Evusheld has been authorized for preventing COVID-19 in **high-risk** individuals. Those that receive the treatment must be 12 years of age or older and weigh at least 40kg/88lbs.[3] High- risk individuals is defined as people who have **moderate to severe immune compromise** due to a medical condition or receipt of immunosuppressive medications or treatments and may not mount an adequate immune response to COVID-19 vaccination (see Figure 1). This also **includes people for whom receiving a 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 its component(s).

Before receiving Evusheld, you should talk with your provider to discuss potential risks and benefits if you[4]:

- Have any allergies
- Have low numbers of blood platelets (which help blood clotting), a bleeding disorder, or are taking anticoagulants (to prevent blood clots)
- Have had a heart attack or stroke, have other heart problems, or are at high risk of cardiac (heart) events
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed
- Have any serious illnesses
- Are taking any medications (prescription, over the counter, vitamins, herbal products, and traditional medicines)

Figure 1: Medical conditions/treatments that may result in moderate to severe immune compromise and an inadequate immune response to COVID19 vaccination include but are not limited to[3]:

- Active treatment for solid tumor and blood, bone marrow, or lymph node cancers
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of chimeric antigen receptor (CAR)-T-cell or bone marrow transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection (people with HIV and low CD4 cell counts)

Evusheld is not authorized for use in people[3]:

- Who have tested positive for COVID-19, or
- Who have already been exposed to someone with COVID-19

How is Evusheld given?

You will receive 1 dose of Evusheld, consisting of 2 separate intramuscular injections given by your healthcare provider. They are usually given one after the other, one into each of your buttocks. After the initial dose, if your healthcare provider determines that you need to receive additional doses of Evusheld for ongoing protection, the additional doses would be administered once every 6 months.[4]

What are the possible benefits of receiving Evusheld?

The known and potential benefits of receiving Evusheld include[2,4]:

- Reduced risk of contracting COVID-19, and therefore:
  - Reduced risk of severe COVID-19 symptoms
  - Reduced risk of hospitalization
  - Reduced risk of death from SARS-CoV-2

What are the possible side effects of receiving Evusheld?

Evusheld is still being studied for its safety and effectiveness, and not all side effects are currently known.[4]

Possible temporary side effects of Evusheld treatment include[3]:

- Allergic reactions including anaphylaxis
- Rash
- Headache
- Chills
- Weakness
- Muscle aches
- Dizziness
- Sweating

Possible temporary side effects of getting any medicine by injection may include[4]:

- Brief pain
- Bleeding
- Bruising of the skin
- Soreness
- Swelling
- Possible infection at the injection site

It is also possible that Evusheld may reduce your body's immune response to a COVID-19 vaccine.[4]

Although not all side effects are currently known, the potential risks continue to be monitored by the FDA.

Can I be vaccinated for COVID-19 if I am treated with Evusheld for COVID-19?

Currently, there is no data on the safety and effectiveness of COVID-19 vaccines in people who received a COVID-19 mAb treatment like Evusheld.

The Advisory Committee on Immunization Practice recommends that you wait 90 days after receiving a COVID-19 mAb treatment to get vaccinated to avoid any possible interactions between the treatment and vaccine. This is the recommended wait time because data suggest that reinfection of COVID-19 is uncommon within 90 days.[5]

Should I continue to follow CDC guidelines?

You should continue to practice all recommended safety measures to stop the spread of COVID-19, even if you have received the Evusheld treatment.

Evusheld may not be effective at preventing COVID-19 caused by certain SARS-CoV-2 variants There is an increased risk of COVID-19 illness if new SARS-CoV-2 variants are not neutralized by Evusheld. You should seek testing and medical attention if you experience COVID-19 signs and symptoms, including alternate treatment.[3]

To further protect yourself and your community we recommend:

- Continuing to wear a mask
- Continuing to social distance
- Continuing to wash your hands
- Following all public health guidelines and recommendations

Resources

1. The COVID-19 Treatment Guidelines Panel's Revised Statement on Tixagevimab Plus Cilgavimab (Evusheld) as Pre-Exposure Prophylaxis of COVID-19. National Institutes of Health. Updated January 30, 2023. Accessed January 30, 2023. https://www.covid19treatmentguidelines.nih.gov/therapies/revised-statement-on-evusheld/?utm_campaign=+54905366&utm_content=&utm_medium=
2. email&utm_source=govdelivery&utm_term=
3. Office of the Commissioner. Coronavirus (COVID-19) Update: FDA Authorizes New Long-Acting Monoclonal Antibodies for Pre-exposure Prevention of COVID-19 in Certain Individuals. U.S. Food and Drug Administration. Published December 8, 2021. Accessed January 26, 2022. https://www.fda.gov/news-events/pressannouncements/coronavirus-covid-19-update-fda-authorizes-new-longacting-monoclonal-antibodies-pre-exposure
4. Fact Sheet for Healthcare Providers: Emergency Use Authorization for Evusheld. U.S. Food and Drug Administration. Accessed October 3, 2022. https://www.fda.gov/media/154701/download
5. Fact Sheet for Patients, Parents and Caregivers Emergency Use Authorization (EUA) of Evusheld for Coronavirus Disease 2019 (COVID19). U.S. Food and Drug Administration. Accessed January 26, 2022. https://www.fda.gov/media/154702/download
6. Interim Clinical Considerations for Use of COVID-19 Vaccines. U.S. Centers for Disease Control and Prevention. Published August 6, 2021. Accessed January 26, 2022. https://www.cdc.gov/vaccines/covid19/clinical-considerations/covid-19-vaccines-us.