**COVID-19 EVUSHELD ™**

**Educational Material and Consent Form**

Patient name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Facility name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of provider conducting informed consent\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Facts about the COVID-19 Emergency Use Authorization (EUA)**

Coronavirus is the virus that causes a disease called COVID-19. The virus is passed from person to person mostly by small droplets. These droplets come from the nose or mouth when an infected person coughs, sneezes, or speaks. Some people who are infected have no symptoms. Others have mild symptoms such as a cough and extreme tiredness. Other people have severe problems and may even die. COVID-19 has caused a worldwide pandemic.

The FDA may grant an EUA when certain standards are met, for instance, when there are no other choices for treating a health problem like COVID-19. The FDA issues EUAs based on scientific proof that shows the product is likely to be safe and effective. Drugs are not reviewed with an EUA in the same way as an FDA-approved or cleared product.

The Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for EVUSHELD ™ for the pre-exposure prophylaxis of COVID-19 in adults and pediatric patients who:

* are 12 years of age and older and weigh at least 88 pounds,
* are not currently infected with COVID-19,
* have not had a known recent exposure to a person infected with COVID-19,
* have moderate to severe immune compromise because of a medical condition or are taking certain drugs that reduce your immune system, or
* anyone who cannot take the vaccination due to a history of severe adverse reaction.

**Risks and Common Problems**

There are risks linked to EVUSHELD ™, which include but are not limited to:

**Allergic reaction:** All kinds of allergic reactions can happen; You could have a minor reaction, such as a rash, or a severe reaction, such as swelling of your lips, face, or throat; A severe allergic reaction is a medical emergency that can cause death.

**Cough**

**Fatigue**

**Headache**

**Heart attacks and heart failure (for anyone with a history of heart disease)**

All drugs can cause side effects. Problems that are not expected may happen. These problems may be life threatening. If you have any severe symptoms after the treatment, seek medical attention immediately.

**Other Choices**

If you decide not to take EVUSHELD ™ then you may have other choices. The FDA may grant emergency use for other drugs for preventative treatment. Your doctor may also talk with you about clinical studies you may be able to join.

**More Facts**

EVUSHELD ™ will be given to you by your healthcare provider as two shots. They are usually given at the same time in two different locations.

EVUSHELD ™ is not authorized for use in people:

* For treatment of COVID-19, or
* For post-exposure prophylaxis of COVID-19 after being exposed to someone infected with COVID-19, or
* Pre-exposure prophylaxis with EVUSHELD ™ is not a substitute for vaccination.

EVUSHELD ™ should be given with caution to people with thrombocytopenia or any bleeding disorder.

Tell your doctor if you have:

* any allergies,
* a bleeding disorder or taking blood thinners,
* had a heart attack or stroke,
* a high risk of heart issues,
* plans to become pregnant or are pregnant or breastfeeding,
* any serious illness, or
* taken any medications (prescription, over the counter, vitamins, or herbal products).

After you get this pretreatment, you will still need to take precautions to avoid being exposed to COVID-19.

It is possible that EVUSHELD ™ may reduce your body’s immune response to a COVID-19 vaccine. If you have received a COVID-19 vaccine, you should wait to receive EVUSHELD ™ until **at least 2 weeks** after COVID-19 vaccination.

**Consent to Treatment**

This consent form told you about the EVUSHELD ™ shots and its most common risks. If, after reviewing this form, you do not believe that you understand the risks and your choices, then **do not sign the form until all your questions have been answered.**

I have given my provider an updated medical history.

I understand the facts provided to me in this consent form, and it is my choice to receive the EVUSHELD ™ shots. I give my consent for this preventative treatment. By signing below, I agree that the staff/doctor has discussed the facts in this form with me, that no one has given me any guarantee about this preventative treatment, that I have had a chance to ask questions, and that all my questions have been answered.

I agree I was given a copy of the EVUSHELD ™ fact sheet today.

I have \_\_\_ no known drug allergies **or** \_\_\_ the drug allergies listed below:

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Signature of Patient or Responsible Party Date and Time

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Relationship to Patient (if Responsible Party is not Patient)

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Witness Date and Time

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Provider Date and Time