

FACT SHEET FOR PATIENTS AND PARENTS/CAREGIVERS

EMERGENCY USE AUTHORIZATION (EUA) OF COVID-19 CONVALESCENT PLASMA FOR TREATMENT OF CORONAVIRUS DISEASE 2019 (COVID-19)

You are being given this Fact Sheet because your healthcare provider believes it is necessary to provide you with COVID-19 convalescent plasma to treat COVID-19. This fact sheet contains information to help you understand the potential risks and potential benefits of taking the COVID-19 convalescent plasma you have received or may receive.

Transfusion of COVID-19 convalescent plasma may benefit patients with COVID-19 and weakened immune systems. In patients with weakened immune systems, their body is unable to make its own antibodies to the virus or the patient may be taking medications that impair their immune system.

This Fact Sheet contains information to help you understand the risks and benefits of COVID-19 convalescent plasma. Talk to your health care provider if you have questions. It is your choice to accept treatment with COVID-19 convalescent plasma or stop it at any time.

WHAT IS COVID-19?

COVID-19 is a disease caused by a coronavirus. You can get COVID-19 through contact with another person who has the virus. COVID-19 illnesses have ranged from very mild (including some with no reported symptoms) to severe, including illness resulting in death. While information so far suggests that most COVID-19 illness is mild, people with deficient or suppressed immune systems may be at increased risk of severe disease or hospitalization due to COVID-19.

WHAT IS COVID-19 CONVALESCENT PLASMA?

COVID-19 convalescent plasma is the liquid portion of blood from donors who have recovered from COVID-19. The blood from people who recover from COVID-19 contains substances called antibodies, which are capable of fighting the virus that causes COVID-19. For some other diseases caused by respiratory viruses, giving people the liquid portion of blood that contains these antibodies, called plasma, obtained from those who have recovered from the virus, may lead to more rapid improvement of the disease. Patients with COVID-19 and weakened immune systems may improve faster if they receive plasma from those who have recovered from COVID-19, because it may have the ability to fight the virus that causes COVID-19.

HOW IS COVID-19 CONVALESCENT PLASMA GIVEN?

You will be given plasma, the liquid portion of the blood, from a person who has recovered from COVID-19. It will be given into one of your veins, using a sterile single use needle, and will be given over the course of up to about one to two hours. Approximately 200 mL (a little less than 8 ounces) of plasma will be given in an initial infusion. Additional infusions of plasma may be given if the treating physician determines that additional treatments are clinically justified.

WHAT ARE THE POSSIBLE BENEFITS OF GETTING COVID-19 CONVALESCENT PLASMA?

This treatment might be effective in improving your symptoms and the likelihood of you recovering from the disease.

WHAT ARE THE COMMON AND/OR POSSIBLE SIDE EFFECTS (RISKS) OF COVID-19 CONVALESCENT PLASMA?

Transfusion carries the risk of adverse reactions such as allergic reactions, fevers, transfusion-associated circulatory overload (too much fluid which leads to breathing difficulty), lung damage with profound breathing difficulty, cardiac (heart) rhythm irregularities, and blood clotting.

As with receipt of any blood product, there is a risk of transfusion-transmitted infection including HIV, hepatitis B, and hepatitis C. The risk of these infections is very low, because only screened blood is used for transfusion.

You may have other side effects that are not known at this time and may include serious injury or pain, disability, or death.

WHO SHOULD NOT GET COVID-19 CONVALESCENT PLASMA?

Discuss with your health care provider if previously you had any reactions to plasma products or other blood products.

WHAT IF I AM PREGNANT OR BREASTFEEDING?

The safety and effectiveness of COVID-19 convalescent plasma in pregnancy and nursing mothers has not been evaluated. If you are pregnant or breastfeeding, please talk with your health care provider to decide if you should receive COVID-19 convalescent plasma.

HOW DO I REPORT SIDE EFFECTS?

After receiving COVID-19 convalescent plasma, if you are experiencing any side effects that are bothersome, serious, or that do not go away, please contact your health care provider. When you are reporting a side effect, you should identify that you received COVID-19 convalescent plasma.

ARE THERE OTHER ALTERNATIVES TO COVID-19 CONVALESCENT PLASMA?

Like COVID-19 convalescent plasma, FDA may allow for the emergency use of other medicines to treat people with COVID-19. Go to <https://www.covid19treatmentguidelines.nih.gov/> for information on other medicines used to treat people with COVID-19. Your healthcare provider may talk to you about clinical trials for which you may be eligible. It is your choice to be treated or not to be treated with COVID-19 convalescent plasma. Should you decide not to receive COVID-19 convalescent plasma or stop it at any time, it will not change your standard medical care.

HOW CAN I LEARN MORE?

- Ask your health care provider
- Contact your local or state public health department

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?

The United States FDA has made COVID-19 convalescent plasma available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

COVID-19 convalescent plasma has not undergone the same type of review as an FDA-approved or cleared product. In issuing an EUA under the COVID-19 public health emergency, the FDA has determined, among other things, that based on the total amount of scientific evidence available, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that the product may be effective for diagnosing, treating, or preventing COVID-19, or a serious or life-threatening disease or condition caused by COVID-19; that the known and potential benefits of the product, when used to diagnose, treat, or prevent such disease or condition, outweigh the known and potential risks of such product; and that there are no adequate, approved and available alternatives.

All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic. The EUA for COVID-19 convalescent plasma is in effect for the duration of the COVID-19 declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).