

On October 22, 2020, FDA approved Veklury (remdesivir) for use in adults and pediatric patients (12 years of age and older and weighing at least 40 kg) for the treatment of COVID-19 requiring hospitalization. Veklury should only be administered in a hospital or in a healthcare setting capable of providing acute care comparable to inpatient hospital care. This approval does not include the entire population that had been authorized to use Veklury under an Emergency Use Authorization (EUA) originally issued on May 1, 2020. In order to ensure continued access to the pediatric population previously covered under the EUA, the EUA for Veklury continues to authorize Veklury for emergency use by licensed healthcare providers for the treatment of suspected or laboratory-confirmed COVID-19 in hospitalized pediatric patients weighing 3.5 kg to less than 40 kg **or** hospitalized pediatric patients less than 12 years of age weighing at least 3.5 kg. Clinical trials assessing the safety and efficacy of Veklury in this pediatric patient population are ongoing. For current EUA documents, please see: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs>.

**Fact Sheet for Patients And Parents/Caregivers
Emergency Use Authorization (EUA) Of Veklury® (remdesivir) For Coronavirus Disease 2019
(COVID-19)**

You are being given a medicine called **Veklury (remdesivir)** for the treatment of coronavirus disease 2019 (COVID-19). This Fact Sheet contains information to help you understand the potential risks and potential benefits of taking Veklury, which you have received or may receive.

There is no U.S. Food and Drug Administration (FDA) approved product available to treat COVID-19. Receiving Veklury may benefit certain people in the hospital with COVID-19. Read this Fact Sheet for information about Veklury. Talk to your healthcare provider if you have questions. It is your choice to receive Veklury or stop it at any time.

What is COVID-19?

COVID-19 is caused by a virus called a coronavirus. This type of coronavirus has not been seen before. 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, serious illness can happen and may cause some of your other medical conditions to become worse. Older people and people of all ages with severe, long-lasting (chronic) medical conditions like heart disease, lung disease, and diabetes, for example, seem to be at higher risk of being hospitalized for COVID-19.

What are the symptoms of COVID-19?

The symptoms of COVID-19 are fever, cough, and shortness of breath, which may appear 2 to 14 days after exposure. Serious illness including breathing problems can occur and may cause your other medical conditions to become worse.

What is Veklury (remdesivir)?

Veklury is an investigational antiviral medicine used for the treatment of certain people in the hospital with COVID-19. Veklury is investigational because it is still being studied. There is limited information known about the safety and effectiveness of using Veklury to treat people in the hospital with COVID-19. Veklury was shown in a clinical trial to shorten the time to recovery in some people. There are no medicines approved by the FDA as safe and effective to treat people in the hospital who have COVID-19. Therefore, the FDA has authorized the emergency use of Veklury for the treatment of COVID-19 under an Emergency Use Authorization (EUA). For more information on EUA, see the “**What is an Emergency Use Authorization (EUA)?**” section at the end of this Fact Sheet.

What should I tell my healthcare provider before I receive Veklury (remdesivir)?

Tell your healthcare provider about all of your medical conditions, including if you:

- Have any allergies
- Have kidney or liver problems
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed
- Have any serious illnesses

- Are taking any medicines (prescription, over-the-counter, vitamins, or herbal products). Veklury may affect the way other medicines work, and other medicines may affect how Veklury works.
 - **Especially tell your healthcare provider if you are taking the medicines chloroquine phosphate or hydroxychloroquine sulfate.**

How will I receive Veklury (remdesivir)?

Veklury is given to you through a vein (intravenous or IV) one time each day for up to 10 days depending on what your healthcare provider thinks is best for you. Veklury may help decrease the amount of the coronavirus in your body. This may help you to get better faster.

What are the important possible side effects of Veklury (remdesivir)?

Possible side effects of Veklury are:

- Allergic reactions. Veklury can cause allergic reactions, including serious reactions, during and after infusion. Tell your healthcare provider or nurse, or get medical help right away if you get any of the following signs and symptoms of allergic reactions: low blood pressure, changes in your heartbeat, shortness of breath, wheezing, swelling of your lips, face, or throat, rash, nausea, vomiting, sweating, or shivering.
- Increases in levels of liver enzymes. Increases in levels of liver enzymes have been seen in people who have received Veklury, which may be a sign of inflammation or damage to cells in the liver. Your healthcare provider will do blood tests to check your liver before you receive Veklury and daily while receiving Veklury.

These are not all the possible side effects of Veklury. Veklury is still being studied so it is possible that all of the risks are not known at this time.

Not a lot of people have taken Veklury. Serious and unexpected side effects may happen. The side effects of getting any medicine by vein may include brief pain, bleeding, bruising of the skin, soreness, swelling, and possible infection at the injection site.

What other treatment choices are there?

Like Veklury, FDA may allow for the emergency use of other medicines to treat people in the hospital with COVID-19. Go to <https://www.covid19treatmentguidelines.nih.gov/> for information on the emergency use of other medicines that are not approved by FDA to treat people in the hospital with COVID-19. Your healthcare provider may talk with you about clinical trials you may be eligible for.

It is your choice to be treated or not to be treated with Veklury. Should you decide not to receive it or stop it at any time, it will not change your standard medical care.

What if I am pregnant or breastfeeding?

There is limited experience giving Veklury to pregnant women or breastfeeding mothers. For a mother and unborn baby, the benefit of receiving Veklury may be greater than the risk from the treatment. If you are pregnant or breastfeeding, discuss your options and specific situation with your healthcare provider.

How do I report side effects with Veklury (remdesivir)?

Tell your healthcare provider right away if you have any side effect that bothers you or does not go away.

Report side effects to **FDA MedWatch** at www.fda.gov/medwatch or call 1-800-FDA-1088.

How can I learn more?

- Ask your healthcare provider.
- Visit <https://www.covid19treatmentguidelines.nih.gov/>
- Contact your local or state public health department.

What is an Emergency Use Authorization (EUA)?

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

Veklury has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that it is reasonable to believe that the product meets certain criteria for safety, performance, and labeling and may be effective in treatment of patients during the COVID-19 pandemic. 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 Veklury (remdesivir) 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).

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