

Patient Education

Remdesivir FDA Fact Sheet

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You must carefully read the "Consumer Information Use and Disclaimer" below in order to understand and correctly use this information

About this topic

**Fact Sheet for Parents and Caregivers
Emergency Use Authorization (EUA) of VEKLURY® (remdesivir) for Hospitalized Children Weighing 8
pounds (3.5 kg) to Less Than 88 pounds (40 kg) or Hospitalized Children Less Than 12 Years of Age
Weighing at least 8 pounds (3.5 kg) with Coronavirus Disease 2019
(COVID-19)**

Your child is being given a medicine called **VEKLURY**. VEKLURY is a medicine approved for adults and children 12 years of age and older and weighing at least 88 pounds (40 kg) for the treatment of coronavirus disease 2019 (COVID-19) requiring hospitalization. It is not known if VEKLURY is safe and effective for the treatment of COVID-19 in hospitalized children weighing 8 pounds (3.5 kg) to less than 88 pounds (40 kg) or hospitalized children less than 12 years of age weighing at least 8 pounds (3.5 kg), and VEKLURY is not FDA approved for this use. This Fact Sheet contains information to help you understand the potential risks and potential benefits of your child receiving VEKLURY.

Read this Fact Sheet for information about VEKLURY. Talk to your healthcare provider if you have questions. It is your choice for your child to receive VEKLURY or to stop it at any time.

What is COVID-19?

COVID-19 is caused by a virus called a coronavirus. People 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 a child's other medical conditions to become worse. 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 child's other medical conditions to become worse.

What is VEKLURY?

VEKLURY is an approved antiviral medicine for adults and children 12 years of age and older and weighing at least 88 pounds (40 kg) for the treatment of COVID-19 requiring hospitalization. VEKLURY was shown in clinical trials in adults to shorten the time to recovery in some people.

VEKLURY is still being studied in hospitalized children.

There are no medicines approved by the FDA as safe and effective to treat hospitalized children weighing 8 pounds (3.5 kg) to less than 88 pounds (40 kg) or hospitalized children younger than 12 years of age weighing at least 8 pounds (3.5 kg) who have COVID-19. Therefore, the FDA has authorized the emergency use of VEKLURY for this use 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 my child receives VEKLURY?

Tell your healthcare provider about all of your child's medical conditions, including if your child:

- Has kidney problems
- Has liver problems
- Is taking any medicines (prescription, over-the-counter, vitamins, or herbal products). VEKLURY may interact with other medicines.
 - **Especially tell your healthcare provider if your child is taking the medicines chloroquine phosphate or hydroxychloroquine sulfate.**

How will my child receive VEKLURY?

VEKLURY is given to your child through a vein (intravenous or IV) one time each day for up to 10 days. Your healthcare provider will decide how many doses your child needs.

What are the important possible side effects of VEKLURY?

Possible side effects of VEKLURY are:

- Allergic reactions. Allergic reactions can happen during and after infusion with VEKLURY. Tell your healthcare provider right away if your child gets any of the following signs and symptoms of allergic reactions: changes to heart rate, fever, shortness of breath, wheezing, swelling of the lips, face, or throat, rash, nausea, sweating, or shivering.
- Increases in levels of liver enzymes. Increases in liver enzymes are common in people who have received VEKLURY and may be a sign of liver injury. Your healthcare provider will do blood tests to check your child's liver enzymes before receiving VEKLURY and as needed while receiving VEKLURY. Your healthcare provider may stop treatment with VEKLURY if your child develops new or worsening liver problems.

The most common side effect of VEKLURY is nausea.

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.

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 hospitalized children weighing 8 pounds (3.5 kg) to less than 88 pounds (40 kg) or hospitalized children younger than 12 years of age weighing at least 8 pounds (3.5 kg) with COVID-19. Go to <https://www.covid19treatmentguidelines.nih.gov/> for information on the emergency use of other medicines that are not approved by the FDA to treat people in the hospital with COVID-19. Your healthcare provider may talk with you about clinical trials your child may be eligible for.

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

How do I report side effects with VEKLURY?

Tell your healthcare provider right away if your child has any side effect that bothers them or does not go away.

Report side effects to **FDA MedWatch** at www.fda.gov/medwatch or call 1-800-FDA-1088 and to **Gilead** by calling 1-800-GILEAD-5.

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 to hospitalized children weighing 8 pounds (3.5 kg) to less than 88 pounds (40 kg) or hospitalized children less than 12 years of age weighing at least 8 pounds (3.5 kg) 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.

The 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 hospitalized children weighing 8 pounds (3.5 kg) to less than 88 pounds (40 kg) or hospitalized children less than 12 years of age weighing at least 8 pounds (3.5 kg) during the COVID-19 pandemic, and that the known and potential benefits outweigh the known and potential risks for such use.

The EUA for VEKLURY is in effect for the duration of the COVID-19 declaration justifying emergency use of the product, unless terminated or revoked (after which the product may no longer be used).

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Remdesivir FDA Fact Sheet: <https://www.fda.gov/media/137565/download>

Report side effects to FDA MedWatch: www.fda.gov/medwatch

CDC: <https://www.cdc.gov/coronavirus/2019-ncov/index.html>

NIH: <https://www.covid19treatmentguidelines.nih.gov/>

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