

**Fact Sheet for Parents and Caregivers
Emergency Use Authorization (EUA) of VEKLURY® (remdesivir) for
Coronavirus Disease 2019 (COVID-19) for Children Weighing 8 pounds (3.5 kg) to
Less Than 88 pounds (40 kg) or for Children Less Than 12 Years of Age Weighing
at least 8 pounds (3.5 kg) who are: hospitalized, or not hospitalized and have mild-
to-moderate COVID-19 and are at high risk for progression to severe COVID-19,
including hospitalization or death**

You are being given this Fact Sheet because your healthcare provider believes it is necessary to provide your child with **VEKLURY** for use for the treatment of coronavirus disease 2019 (COVID-19). The United States Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for VEKLURY for use in children weighing 8 pounds (3.5 kg) to less than 88 pounds (40 kg) **or** children less than 12 years of age weighing at least 8 pounds (3.5 kg) with positive results of direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing, who are:

- hospitalized, **or**
- not hospitalized and have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death.

This Fact Sheet contains information to help you understand the risks and benefits of your child receiving VEKLURY.

The FDA has issued an EUA to make VEKLURY available for this use during the COVID-19 pandemic (for more details about an EUA please see “**What is an Emergency Use Authorization?**” at the end of this document). VEKLURY is not approved for use as treatment for COVID-19 for the pediatric population covered under this EUA. Read this Fact Sheet for information about VEKLURY. Talk to your healthcare provider about your options or if you have any questions. It is your choice for your child to receive VEKLURY or stop it at any time.

What is COVID-19?

COVID-19 is caused by a virus called a coronavirus. You can get COVID-19 through close contact with another person who has the virus.

COVID-19 illnesses have ranged from very mild to severe, including illness with no reported symptoms and 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. 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 is VEKLURY?

VEKLURY is a prescription medicine that is investigational for use for the treatment of COVID-19 in children weighing 8 pounds (3.5 kg) to less than 88 pounds (40 kg) **or** children less than 12 years of age weighing at least 8 pounds (3.5 kg) with positive results of direct SARS-CoV-2 viral testing, who are:

- hospitalized, **or**
- not hospitalized and have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death.

VEKLURY is investigational for this use because it is still being studied and there is limited information about the safety and effectiveness of using VEKLURY for the treatment of COVID-19 in this population.

VEKLURY is an FDA-approved prescription medicine used to treat COVID-19 in adults and children (12 years of age and older and weighing at least 88 pounds (40 kg)), with positive results of direct SARS-CoV-2 viral testing, who are:

- hospitalized, or
- not hospitalized and have mild-to-moderate COVID-19, and at high risk for progression to severe COVID-19, including hospitalization or death.

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 any allergies
- Has kidney or liver disease
- Has any serious illnesses

Tell your healthcare provider about all the medicines your child takes, including prescription and over-the-counter medicines, vitamins, and herbal supplements. VEKLURY may interact with other medicines and may cause serious side effects.

Especially tell your healthcare provider if your child is taking the medicines chloroquine phosphate or hydroxychloroquine sulfate.

How will my child receive VEKLURY?

- **Hospitalized:** VEKLURY is given to your child through a vein by intravenous (IV) infusion one time each day for up to 10 days. Your healthcare provider will decide how many doses your child needs.
- **Not hospitalized:** VEKLURY is given to your child through a vein by intravenous (IV) infusion one time each day for 3 days.
- Your healthcare provider will do certain blood tests before starting and during treatment with VEKLURY.

Who should generally not receive VEKLURY?

Your child should not receive VEKLURY if your child is allergic to remdesivir or any of the ingredients in VEKLURY.

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. Your healthcare provider will monitor your child for signs and symptoms of allergic reactions during their infusion and for at least 1 hour after their infusion. Tell your healthcare provider right away if your child gets any of the following signs and symptoms of allergic reactions:

○ changes to heart rate	○ swelling of the lips, face, or throat
○ fever	○ rash
○ shortness of breath or wheezing	○ nausea
○ shivering	○ sweating
- **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 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.

What other treatment choices are there?

Like VEKLURY, FDA may allow for the emergency use of other medicines to treat people with COVID-19. Go to <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy->

framework/emergency-use-authorization for information on the emergency use of other medicines that are not approved by the FDA to treat people 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 for your child not to receive it, it will not change your child's standard medical care.

How do I report side effects with VEKLURY?

Contact your healthcare provider 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 1-800-445-3235.

How can I learn more about COVID-19?

- Ask your healthcare provider.
- Visit <https://www.cdc.gov/COVID19>.
- 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 Emergency Use Authorization (EUA) for the treatment of coronavirus disease 2019 (COVID-19) in children weighing 8 pounds (3.5 kg) to less than 88 pounds (40 kg) or children 12 years of age weighing at least 8 pounds (3.5 kg), with positive results of direct sequence real-time reverse transcriptase polymerase chain reaction (RT-PCR) testing for respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing, who are:

- hospitalized, **or**
- not hospitalized and have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death.

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 for the authorized use has not undergone the same type of review as an FDA-approved 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, 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 the authorized patient population during the COVID-19 pandemic. The EUA for VEKLURY is in effect for the duration of the COVID-19 declaration justifying emergency use of VEKLURY, unless terminated or revoked (after which VEKLURY may no longer be used under the EUA).

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