



## IMPORTANT PRESCRIBING INFORMATION

**Subject:** Updated Emergency Use Authorization (EUA) for 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 with suspected or laboratory-confirmed COVID-19 and variations in carton and vial labeling of VEKLURY® (remdesivir)

Dear Healthcare Provider:

Gilead Sciences, Inc., would like to clarify the appropriate use and the variable packaging and labeling of the antiviral **VEKLURY® (remdesivir)**.

Gilead's remdesivir (brand name VEKLURY) was approved by the US Food and Drug Administration (FDA) on October 22, 2020, for adults and pediatric patients (12 years and older and weighing at least 40 kg) for the treatment of coronavirus disease 2019 (COVID-19) requiring hospitalization. Healthcare providers should administer VEKLURY in these patients per the current US Prescribing Information available at [www.gilead.com/science-and-medicine/medicines](http://www.gilead.com/science-and-medicine/medicines); please also see Important Safety Information at the end of this letter.

**Emergency use of Gilead's remdesivir (brand name VEKLURY) 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 with suspected or laboratory-confirmed COVID-19**

On October 22, 2020, FDA revised the Emergency Use Authorization (EUA) for VEKLURY, which now authorizes VEKLURY for use by healthcare providers to treat 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 with suspected or laboratory-confirmed COVID-19. Only Gilead's VEKLURY (remdesivir) for injection (supplied as 100 mg lyophilized powder in vial) is authorized for emergency use under the terms and conditions set forth in the Letter of Authorization for the EUA.

The safety and efficacy of VEKLURY 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 for the treatment of suspected or laboratory-confirmed COVID-19 has not been established, and VEKLURY is not FDA approved for this use. For information about the authorized use of VEKLURY 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, including dosing, administration, and preparation instructions, please review the EUA Fact Sheet for Healthcare Providers and FDA Letter of Authorization

available at [www.gilead.com/remdesivir](http://www.gilead.com/remdesivir).

**Variations in packaging and labeling of Gilead’s remdesivir (brand name VEKLURY)**

Gilead’s VEKLURY (remdesivir) has been manufactured for use under an EUA, and for commercial use. As such, VEKLURY has different packaging, labeling, and expiration dates depending on the date of manufacture. Packaging and labeling for Gilead’s remdesivir EUA use may not necessarily include the brand name, VEKLURY.

**To help avoid potential drug shortage, hospitals should continue to use all unexpired, unopened vials of Gilead’s remdesivir – whether or not the vial includes the brand name VEKLURY or is labeled for use under EUA.** Refer to the attached chart at the end of this letter that outlines what hospitals should do with unexpired, unopened vials of Gilead’s remdesivir.

Authentic VEKLURY or remdesivir, manufactured by Gilead Sciences, Inc., will include the GILEAD name and logo on the carton and vial label. All packaging includes the drug name remdesivir. Current packaging variations for the two formulations are described below. Both formulations are for intravenous infusion only.

- **VEKLURY® (remdesivir) for injection (supplied as 100 mg lyophilized powder in vial).** The lyophilized powder formulation is always supplied with a red cap and the package and labeling may be marked “for use under Emergency Use Authorization (EUA)”.
- **VEKLURY® (remdesivir) injection (supplied as 100 mg/20 mL [5 mg/mL], solution in vial).** The solution formulation is supplied with a blue cap and the package and labeling may be marked “for use under Emergency Use Authorization (EUA)”. **The solution should only be used in adults and pediatric patients 12 years of age and older and weighing at least 40 kg.**

VEKLURY (remdesivir) injection (solution; left) and VEKLURY (remdesivir) for injection (lyophilized powder; right) now approved by FDA for use in accordance with the prescribing information (PI).



VEKLURY (remdesivir) injection (solution; left) and VEKLURY (remdesivir) for injection (lyophilized powder; right) previously authorized for emergency use.



## **Reporting Adverse Events and Medication Errors**

Healthcare providers should direct questions on VEKLURY packaging or use to Gilead Sciences at 1-866-633-4474 or [www.askgileadmedical.com](http://www.askgileadmedical.com).

Healthcare providers are encouraged to report all adverse events and medication errors when utilizing VEKLURY to Gilead Sciences at [Safety\\_fc@gilead.com](mailto:Safety_fc@gilead.com). Adverse reactions, medication errors, or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online**: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)
- **Regular Mail or Fax**: Download form <https://www.accessdata.fda.gov/scripts/medwatch/index.cfm> or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178 (1-800-332-0178).

For emergency use 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, healthcare providers and/or their designee are responsible for mandatory FDA MedWatch reporting of all medication errors and serious adverse events or deaths occurring during VEKLURY treatment and considered to be potentially attributable to VEKLURY. These events must be reported within 7 calendar days from the onset of the event. MedWatch adverse event reports can be submitted to FDA online at [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or by calling 1-800-FDA-1088.

For additional information about VEKLURY, including the Prescribing Information, please visit [www.vekluryhcp.com](http://www.vekluryhcp.com).

Information and reports of suspicious, counterfeit, or unregistered remdesivir can be submitted to Gilead [anticounterfeiting@gilead.com](mailto:anticounterfeiting@gilead.com) and/or [www.fraud.org/fakerx](http://www.fraud.org/fakerx).



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Appropriate use of Gilead’s remdesivir (brand name VEKLURY), including vials labeled for Emergency Use Authorization (EUA) use		
Product	Remdesivir for injection, 100 mg, lyophilized powder	Remdesivir injection, 100 mg/20 mL (5 mg/mL), solution
Labeled “For use under Emergency Use Authorization (EUA)” (vials and cartons do not include the brand name, VEKLURY)	Continue use in: <ul style="list-style-type: none"> <li>Adults and pediatric patients (12 years of age and older and weighing at least 40 kg) requiring hospitalization</li> <li>Hospitalized pediatric patients weighing 3.5 kg to less than 40 kg <u>or</u> hospitalized pediatric patients less than 12 years of age weighing at least 3.5 kg <b>under the provisions of the Emergency Use Authorization (EUA) – Please review the EUA Fact Sheet for Healthcare Providers and FDA Letter of Authorization, available at <a href="http://gilead.com/remdesivir">gilead.com/remdesivir</a>.</b></li> </ul>	Continue use in: <ul style="list-style-type: none"> <li>Adults and pediatric patients (12 years of age and older and weighing at least 40 kg) requiring hospitalization</li> </ul>
FDA-approved VEKLURY (carton and vials will include the brand name, VEKLURY)	Use in: <ul style="list-style-type: none"> <li>Adults and pediatric patients (12 years of age and older and weighing at least 40 kg) requiring hospitalization</li> <li>Hospitalized pediatric patients weighing 3.5 kg to less than 40 kg <u>or</u> hospitalized pediatric patients less than 12 years of age weighing at least 3.5 kg <b>under the provisions of the Emergency Use Authorization (EUA) – Please review the EUA Fact Sheet for Healthcare Providers and FDA Letter of Authorization, available at <a href="http://gilead.com/remdesivir">gilead.com/remdesivir</a>.</b></li> </ul>	Use in: <ul style="list-style-type: none"> <li>Adults and pediatric patients (12 years of age and older and weighing at least 40 kg) requiring hospitalization</li> </ul>

## U.S. Indication and Important Safety Information for VEKLURY® (remdesivir)

### Indication

VEKLURY is indicated for adults and pediatric patients (12 years of age and older and weighing at least 40 kg) for the treatment of coronavirus disease 2019 (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.

### Important Safety Information

#### Contraindication

- VEKLURY is contraindicated in patients with a history of clinically significant hypersensitivity reactions to VEKLURY or any of its components.

### Warnings and precautions

- Hypersensitivity, including infusion-related and anaphylactic reactions: Hypersensitivity, including infusion-related and anaphylactic reactions, has been observed during and following administration of VEKLURY. Monitor patients under close medical supervision for hypersensitivity reactions during and following administration of VEKLURY. Symptoms may include hypotension, hypertension, tachycardia, bradycardia, hypoxia, fever, dyspnea, wheezing, angioedema, rash, nausea, diaphoresis, and shivering. Slower infusion rates (maximum infusion time ≤120 minutes) can potentially prevent these reactions. If a severe infusion-related hypersensitivity reaction occurs, immediately discontinue VEKLURY and initiate appropriate treatment (see Contraindications).
- Increased risk of transaminase elevations: Transaminase elevations have been observed in healthy volunteers and in patients with COVID-19 who received VEKLURY; these elevations have also been reported as a clinical feature of COVID-19. Perform hepatic laboratory testing in all patients (see Dosage and administration). Consider discontinuing VEKLURY if ALT levels increase to >10x ULN. Discontinue VEKLURY if ALT elevation is accompanied by signs or symptoms of liver inflammation.
- Risk of reduced antiviral activity when coadministered with chloroquine or hydroxychloroquine: Coadministration of VEKLURY with chloroquine phosphate or hydroxychloroquine sulfate is not recommended due to antagonism observed in cell culture, which may lead to a decrease in antiviral activity of VEKLURY

### **Adverse reactions**

- The most common adverse reaction (≥5% all grades) was nausea.
- The most common lab abnormalities (≥5% all grades) were increases in ALT and AST.

### **Drug interactions**

- Drug interaction trials of VEKLURY and other concomitant medications have not been conducted in humans.

### **Dosage and administration**

- Dosage: For adults and pediatric patients ≥12 years old and weighing ≥40 kg: 200 mg on Day 1, followed by once-daily maintenance doses of 100 mg from Day 2 administered only via intravenous infusion over 30 to 120 minutes.
- Treatment duration: For patients not requiring invasive mechanical ventilation and/or extracorporeal membrane oxygenation (ECMO): 5 days; may be extended up to 5 additional days (10 days total) if clinical improvement is not observed. For patients requiring invasive mechanical ventilation and/or ECMO: 10 days.
- Testing prior to and during treatment: Perform eGFR, hepatic laboratory, and prothrombin time testing prior to initiating VEKLURY and during use as clinically appropriate.
- Renal impairment: VEKLURY is not recommended in individuals with eGFR <30 mL/min.
- Dose preparation and administration: See full Prescribing Information.

**Pregnancy and lactation**

- Pregnancy: There are insufficient human data on the use of VEKLURY during pregnancy. Pregnant women hospitalized with COVID-19 are at risk for serious morbidity and mortality. VEKLURY should be used during pregnancy only if the potential benefit justifies the potential risk for the mother and the fetus.
- Lactation: It is not known whether VEKLURY can pass into breast milk. Breastfeeding individuals with COVID-19 should follow practices according to clinical guidelines to avoid exposing the infant to COVID-19.

Please see full Prescribing Information for VEKLURY, available at [www.gilead.com](http://www.gilead.com).