



## IMPORTANT PRESCRIBING INFORMATION

**Subject: Inconsistencies between VEKLURY® (remdesivir) Prescribing Information and VEKLURY for injection (supplied as lyophilized powder in vial) container label and carton labeling may lead to medication errors in pediatric patients.**

Dear Healthcare Provider:

Gilead Sciences, Inc., would like to alert providers that the **preparation and storage information on the container label and carton labeling of VEKLURY® (remdesivir) for injection (supplied as lyophilized powder in vial) may be inconsistent** with the US Prescribing Information that was revised on 25 April 2022 to include pediatric patients 28 days and older and weighing 3 kg to less than 40 kg.

To prevent medication errors, **healthcare providers should refer to the Dosage and Administration (Sections 2.6 and 2.7) of the most currently approved US Prescribing Information to prepare doses for pediatric patients 28 days and older and weighing 3 kg to less than 40 kg.** The current US Prescribing Information is available at [www.gilead.com/science-and-medicine/medicines](http://www.gilead.com/science-and-medicine/medicines).

VEKLURY is available in two injectable dosage forms, a solution and lyophilized powder. **Only the VEKLURY for injection dosage form (supplied as lyophilized powder in vial) is approved for pediatric patients 28 days and older and weighing 3 kg to less than 40 kg.**

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

Healthcare providers are encouraged to report all adverse events and all medication errors when using VEKLURY to Gilead Sciences at [Safety\\_fc@gilead.com](mailto:Safety_fc@gilead.com) and to FDA online at [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or by calling 1-800-FDA-1088.

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).

For additional information about VEKLURY, including the full Prescribing Information, please visit [www.vekluryhcp.com](http://www.vekluryhcp.com). Please also see Important Safety Information at the end of this letter.

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).

*Fernando A. Bognar*

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

### Indication

VEKLURY is indicated for the treatment of COVID-19 in adults and pediatric patients ( $\geq 28$  days old and weighing  $\geq 3$  kg) with positive results of SARS-CoV-2 viral testing, who are:

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

### 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; most occurred within 1 hour. Monitor patients during infusion and observe for at least 1 hour after infusion is complete for signs and symptoms of hypersensitivity as clinically appropriate. Symptoms may include hypotension, hypertension, tachycardia, bradycardia, hypoxia, fever, dyspnea, wheezing, angioedema, rash, nausea, diaphoresis, and shivering. Slower infusion rates (maximum infusion time of up to 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 based on data from cell culture experiments, demonstrating potential antagonism, which may lead to a decrease in the antiviral activity of VEKLURY.

#### Adverse reactions

- The most common adverse reaction ( $\geq 5\%$  all grades) was nausea.
- The most common lab abnormalities ( $\geq 5\%$  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 weighing  $\geq 40$  kg: 200 mg on Day 1, followed by once-daily maintenance doses of 100 mg from Day 2, administered only via intravenous infusion.
  - For pediatric patients  $\geq 28$  days old and weighing  $\geq 3$  kg to  $< 40$  kg: 5 mg/kg on Day 1, followed by once-daily maintenance doses of 2.5 mg/kg from Day 2, administered only via intravenous infusion.
  - There are two different formulations of VEKLURY: VEKLURY for injection (supplied as 100 mg lyophilized powder in vial) and VEKLURY injection (supplied as 100 mg/20 mL [5 mg/mL] solution in vial). The only approved dosage form for pediatric patients weighing 3 kg to  $< 40$  kg is the lyophilized powder formulation; See full Prescribing Information.
- **Treatment duration:**
  - For patients who are hospitalized and require invasive mechanical ventilation and/or ECMO, the recommended total treatment duration is 10 days. VEKLURY should be initiated as soon as possible after diagnosis of symptomatic COVID-19.
  - For patients who are hospitalized and do not require invasive mechanical ventilation and/or ECMO, the recommended treatment duration is 5 days. If a patient does not demonstrate clinical improvement, treatment may be extended for up to 5 additional days, for a total treatment duration of up to 10 days.
  - For patients who are not hospitalized, diagnosed with mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death, the recommended total treatment duration is 3 days. VEKLURY should be initiated as soon as possible after diagnosis of symptomatic COVID-19 and within 7 days of symptom onset.
- **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:**
  - There are two different formulations of VEKLURY: VEKLURY for injection (supplied as 100 mg lyophilized powder in vial), the only approved dosage form of VEKLURY for pediatric patients weighing 3 kg to  $< 40$  kg; and VEKLURY injection (supplied as 100 mg/20 mL [5 mg/mL] solution in vial). See full Prescribing Information.
  - Administration should be under conditions where management of severe hypersensitivity reactions, such as anaphylaxis, is possible.

## Pregnancy and lactation

- **Pregnancy:** A pregnancy registry has been established. There are insufficient

human data on the use of VEKLURY during pregnancy. COVID-19 is associated with adverse maternal and fetal outcomes, including preeclampsia, eclampsia, preterm birth, premature rupture of membranes, venous thromboembolic disease, and fetal death.

- **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).