

VEKLURY® (remdesivir) for Injection (100 mg) Lyophilized Powder

VEKLURY has been issued an Emergency Use Authorization (EUA) by the FDA for the treatment of coronavirus disease 2019 (COVID-19). VEKLURY is an investigational drug that has not been approved by the FDA for any use. It is not yet known if VEKLURY is safe and effective for the treatment of COVID-19. The distribution of VEKLURY has been authorized only for the treatment of hospitalized patients with COVID-19. For more information on the use of VEKLURY, including mandatory adverse event reporting, see the [Fact Sheet for Healthcare Providers](#), available at www.gilead.com/remdesivir.

ADULT DOSE PREPARATION

- 1 Remove the required number of single-dose vial(s) from storage.
- 2 For each vial, aseptically reconstitute VEKLURY (remdesivir) lyophilized powder by addition of 19 mL of Sterile Water for Injection using a suitably sized syringe and needle. Discard the vial if a vacuum does not pull the Sterile Water for Injection into the vial. Care should be taken during admixture to prevent inadvertent microbial contamination.
- 3 Immediately shake the vial for 30 seconds.
- 4 Allow the contents of the vial to settle for 2 to 3 minutes. A clear solution should result. If the contents of the vial are not completely dissolved, shake the vial again for 30 seconds and allow the contents to settle for 2 to 3 minutes. Repeat this procedure as necessary until the contents of the vial are completely dissolved.
- 5 Following reconstitution, each vial contains 100 mg/20 mL (5 mg/mL) of remdesivir solution. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.
- 6 After reconstitution, the total storage time before administration should not exceed 4 hours at room temperature or 24 hours at refrigerated temperature (2°C to 8°C [36°F to 46°F]).

DILUTION

- 7 Using **TABLE 1**, determine the volume of 0.9% sodium chloride to withdraw from the infusion bag.
- 8 Withdraw and discard the required volume of 0.9% sodium chloride from the bag per **TABLE 1** using an appropriately sized syringe and needle.
- 9 Withdraw the required volume of reconstituted VEKLURY (remdesivir) for injection from the VEKLURY (remdesivir) vial using an appropriately sized syringe per **TABLE 1**. Discard any unused portion remaining in the VEKLURY (remdesivir) vial.
- 10 Transfer the required volume of reconstituted VEKLURY (remdesivir) for injection to the selected infusion bag.
- 11 Gently invert the bag 20 times to mix the solution in the bag. Do not shake.

TABLE 1. Recommended Dilution Instructions Using Reconstituted VEKLURY (remdesivir) for Injection Lyophilized Powder in Adults and Pediatric Patients Weighing ≥40 kg

VEKLURY (remdesivir) dose	0.9% sodium chloride infusion bag volume to be used	Volume to be withdrawn and discarded from 0.9% sodium chloride infusion bag	Required volume of reconstituted VEKLURY (remdesivir) for injection
200 mg (2 vials)	250 mL	40 mL	40 mL (2 x 20 mL)
	100 mL	40 mL	40 mL (2 x 20 mL)
100 mg (1 vial)	250 mL	20 mL	20 mL
	100 mL	20 mL	20 mL

Storage: The prepared diluted solution is stable for 4 hours at room temperature (20°C to 25°C [68°F to 77°F]) or 24 hours in the refrigerator at 2°C to 8°C (36°F to 46°F).

ADMINISTRATION

Administer the diluted solution with the infusion rate described in **TABLE 2**. After infusion is complete, flush with 0.9% sodium chloride.

TABLE 2. Recommended Rate of Infusion—Diluted VEKLURY (remdesivir) for Injection Lyophilized Powder in Adults and Pediatric Patients Weighing ≥40 kg

Infusion bag volume	Infusion time	Rate of infusion
250 mL	30 minutes	8.33 mL/min
	60 minutes	4.17 mL/min
	120 minutes	2.08 mL/min
100 mL	30 minutes	3.33 mL/min
	60 minutes	1.67 mL/min
	120 minutes	0.83 mL/min

For information about the dosing and administration for pediatric patients weighing 3.5 kg to <40 kg, please refer to the [Fact Sheet for Healthcare Providers](#). For patients weighing <40 kg, use the lyophilized powder formulation only. Please see [Authorized Use and Important Information on pages 4-5](#).

IMPORTANT: VEKLURY must be administered intravenously. The optimal dosing and duration of VEKLURY for the treatment of COVID-19 is unknown. The suggested dose under this EUA is described in the [Fact Sheet for Healthcare Providers](#), available at www.gilead.com/remdesivir. The suggested dose and duration may be updated as data from clinical trials becomes available.

VEKLURY® (remdesivir) Injection, 100 mg/20 mL (5 mg/mL), Solution

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ADULT DOSE PREPARATION

- 1 Remove the required number of single-dose vial(s) from storage. For each vial, equilibrate to room temperature (20°C to 25°C [68°F to 77°F]). Sealed vials can be stored up to 12 hours at room temperature prior to dilution.
- 2 Inspect the vial to ensure the container closure is free from defects and the solution is free of particulate matter.

DILUTION

- 3 Using **TABLE 3**, determine the volume of 0.9% sodium chloride to withdraw from the infusion bag.
- 4 Withdraw and discard the required volume of 0.9% sodium chloride from the bag per **TABLE 3** using an appropriately sized syringe and needle. Care should be taken during admixture to prevent inadvertent microbial contamination.
- 5 Withdraw the required volume of VEKLURY (remdesivir) injection solution from the VEKLURY (remdesivir) vial using an appropriately sized syringe per **TABLE 3**. Pull the syringe plunger rod back to fill the syringe with approximately 10 mL of air. Inject the air into the VEKLURY (remdesivir) injection vial above the level of the solution. Invert the vial and withdraw the required volume of VEKLURY (remdesivir) injection solution into the syringe. The last 5 mL of solution requires more force to withdraw. Discard any unused portion remaining in the VEKLURY (remdesivir) vial.
- 6 Transfer the required volume of VEKLURY (remdesivir) injection solution to the selected infusion bag.
- 7 Gently invert the bag 20 times to mix the solution in the bag. Do not shake.

TABLE 3. Recommended Dilution Instructions—VEKLURY (remdesivir) Solution in Adults and Pediatric Patients Weighing ≥40 kg

VEKLURY (remdesivir) dose	0.9% sodium chloride infusion bag volume to be used	Volume to be withdrawn and discarded from 0.9% sodium chloride infusion bag	Required volume of VEKLURY (remdesivir) injection solution
200 mg (2 vials)	250 mL	40 mL	40 mL (2 x 20 mL)
100 mg (1 vial)		20 mL	20 mL

Storage: The prepared diluted solution is stable for 4 hours at room temperature (20°C to 25°C [68°F to 77°F]) or 24 hours in the refrigerator at 2°C to 8°C (36°F to 46°F).

ADMINISTRATION

Administer the diluted solution with the infusion rate described in **TABLE 4**. After infusion is complete, flush with 0.9% sodium chloride.

TABLE 4. Recommended Rate of Infusion—Diluted VEKLURY (remdesivir) Solution in Adults and Pediatric Patients Weighing ≥40 kg

Infusion bag volume	Infusion time	Rate of infusion
250 mL	30 minutes	8.33 mL/min
	60 minutes	4.17 mL/min
	120 minutes	2.08 mL/min

For information about the dosing and administration for pediatric patients weighing 3.5 kg to <40 kg, please refer to the [Fact Sheet for Healthcare Providers](#). For patients weighing <40 kg, use the lyophilized powder formulation only. Please see [Authorized Use and Important Information](#) on pages 4-5.

IMPORTANT: VEKLURY must be administered intravenously. The optimal dosing and duration of VEKLURY for the treatment of COVID-19 is unknown. The suggested dose under this EUA is described in the [Fact Sheet for Healthcare Providers](#), available at www.gilead.com/remdesivir. The suggested dose and duration may be updated as data from clinical trials becomes available.

Frequently Asked Questions

VEKLURY has been issued an Emergency Use Authorization (EUA) by the FDA for the treatment of coronavirus disease 2019 (COVID-19). VEKLURY is an investigational drug that has not been approved by the FDA for any use. It is not yet known if VEKLURY is safe and effective for the treatment of COVID-19. The distribution of VEKLURY has been authorized only for the treatment of hospitalized patients with COVID-19. For more information on the use of VEKLURY, including mandatory adverse event reporting, see the [Fact Sheet for Healthcare Providers](#), available at www.gilead.com/remdesivir.

What is the authorized use of VEKLURY under the Emergency Use Authorization?

VEKLURY® (remdesivir) is authorized for use under an EUA only for the treatment of adult and pediatric patients hospitalized with suspected or laboratory-confirmed COVID-19, and for whom use of an intravenous (IV) agent is clinically appropriate. VEKLURY must be administered via IV infusion. See the [Fact Sheet for Healthcare Providers](#) for additional information on the storage, handling, preparation, and administration of VEKLURY (remdesivir) IV solution.

What is the product description for VEKLURY (remdesivir)?

Lyophilized Powder

VEKLURY (remdesivir) for injection, 100 mg, is a sterile, preservative-free lyophilized powder that is to be reconstituted with 19 mL of Sterile Water for Injection and further diluted into 0.9% sodium chloride infusion bag prior to administration by intravenous (IV) infusion. Following reconstitution, each vial contains 100 mg/20 mL (5 mg/mL) VEKLURY (remdesivir) reconcentrated solution. VEKLURY (remdesivir) for injection, 100 mg, is supplied in a single-dose clear glass vial. The appearance of the lyophilized powder is white to off-white to yellow. The color does not affect, nor is it indicative of, product stability. The container closure is not made with natural rubber latex. In addition to the active ingredient, the inactive ingredients are sulfobutylether- β -cyclodextrin (SBECD) sodium salt (3 g); Water for Injection, USP, and may include hydrochloric acid and/or sodium hydroxide for pH adjustment.

Injection Solution

VEKLURY (remdesivir) injection, 100 mg/20 mL (5 mg/mL), is a sterile, preservative-free, clear, colorless to yellow, aqueous-based concentrated solution that is to be diluted into 0.9% sodium chloride infusion bag prior to administration by IV. Each single-dose vial of VEKLURY (remdesivir) injection contains 100 mg/20 mL (5 mg/mL). VEKLURY (remdesivir) injection, 100 mg/20 mL (5 mg/mL), is supplied in a single-dose clear glass vial. The container closure is not made with natural rubber latex. In addition to the active ingredient, the inactive ingredients are sulfobutylether- β -cyclodextrin (SBECD) sodium salt (6 g); Water for Injection, USP, and may include hydrochloric acid and/or sodium hydroxide for pH adjustment.

How should VEKLURY (remdesivir) be stored prior to use?

Lyophilized Powder

Store VEKLURY (remdesivir) for injection, 100 mg, vials below 30°C (below 86°F) until required for use. Do not use after expiration date. The lyophilized powder must be reconstituted and diluted prior to use.

Injection Solution

Store VEKLURY (remdesivir) injection, 100 mg/20 mL (5 mg/mL), vials at refrigerated temperature (2°C to 8°C [36°F to 46°F]) until required for use. Do not use after expiration date. Dilute within the same day as administration. Prior to dilution, equilibrate VEKLURY (remdesivir) injection to room temperature (20°C to 25°C [68°F to 77°F]). Sealed vials can be stored up to 12 hours at room temperature prior to dilution. The concentrated solution must be diluted prior to use.

Can any portion of unused VEKLURY (remdesivir) be reused?

Do not reuse or save unused VEKLURY (remdesivir) lyophilized powder, injection solution, or diluted solution for infusion for future use. This product contains no preservative. Maintain adequate records showing receipt, use, and disposition of VEKLURY (remdesivir). For unused intact vials, maintain adequate records showing disposition of VEKLURY (remdesivir); do not discard unused intact vials.

Is VEKLURY (remdesivir) compatible with other IV medications? What other diluents can be used for dilution?

The prepared diluted solution should not be administered simultaneously with any other medication. The compatibility of VEKLURY (remdesivir) injection with IV solutions and medications other than 0.9% sodium chloride is not known. VEKLURY (remdesivir) for injection (100 mg lyophilized powder) must be reconstituted with Sterile Water for Injection and diluted in 0.9% sodium chloride. VEKLURY (remdesivir) injection, 100 mg/20 mL (5 mg/mL solution) must be diluted in 0.9% sodium chloride.

Am I required to report adverse events for VEKLURY?

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 or by calling 1-800-FDA-1088.

For more information, please refer to the [Fact Sheet for Healthcare Providers](#). Please see *Authorized Use and Important Information on pages 4-5*.

SARS-CoV=severe acute respiratory syndrome coronavirus; USP=United States Pharmacopeia.

IMPORTANT: VEKLURY must be administered intravenously. The optimal dosing and duration of VEKLURY for the treatment of COVID-19 is unknown. The suggested dose under this EUA is described in the [Fact Sheet for Healthcare Providers](#), available at www.gilead.com/remdesivir. The suggested dose and duration may be updated as data from clinical trials becomes available.

Authorized Use

VEKLURY® (remdesivir) is authorized for use under an EUA only for the treatment of adult and pediatric patients hospitalized with suspected or laboratory-confirmed COVID-19, and for whom use of an intravenous (IV) agent is clinically appropriate. VEKLURY must be administered via IV infusion.

Important Information

The Secretary of the Department of Health and Human Services has declared a public health emergency that justifies the emergency use of VEKLURY to treat coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2 infection. In response, the U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the unapproved product, VEKLURY, for the treatment of COVID-19.

- VEKLURY is an investigational drug that has not been approved by the FDA for any use. It is not yet known if VEKLURY is safe and effective for the treatment of COVID-19.
- The distribution of VEKLURY has been authorized only for the treatment of hospitalized patients with COVID-19. This use is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use, unless the authorization is terminated or revoked sooner.
- The FDA issued this EUA, requested by Gilead Sciences and based on their submitted data. The FDA Letter of Authorization for the EUA is available at www.gilead.com/remdesivir.

Additional Information for Healthcare Providers:

- Healthcare providers should review the [Fact Sheet for Healthcare Providers](#) for information on the authorized use of VEKLURY and mandatory requirements of the EUA.
- VEKLURY must be administered intravenously. The optimal duration of treatment for COVID-19 is unknown. The suggested dose durations under this EUA are described in the [Fact Sheet for Healthcare Providers](#), available at www.gilead.com/remdesivir.
- 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 the FDA online at www.fda.gov/medwatch, or by calling 1-800-FDA-1088.

Safety Information

VEKLURY is an unapproved investigational product, and there are limited clinical data available. Serious and unexpected adverse events may occur that have not been previously reported with VEKLURY use.

Warnings and precautions:

- Hypersensitivity reactions, including infusion-related and anaphylactic reactions, have been observed during and following administration of VEKLURY. Slower infusion rates, with a maximum infusion time of up to 120 minutes, can be considered to potentially prevent symptoms of hypersensitivity. If signs and symptoms of a clinically significant hypersensitivity reaction occur, immediately discontinue administration of VEKLURY and initiate appropriate treatment. The use of VEKLURY is contraindicated in patients with known hypersensitivity to VEKLURY.
- Transaminase elevations have been observed in healthy volunteers and patients with COVID-19 in clinical trials who received VEKLURY. Do not initiate VEKLURY in patients with ALT $\geq 5x$ ULN; discontinue therapy in patients who develop ALT $\geq 5x$ ULN or ALT elevation accompanied by signs or symptoms of liver inflammation or increasing conjugated bilirubin, alkaline phosphatase, or INR.
- Risk of reduced antiviral activity when coadministered with chloroquine or hydroxychloroquine. Coadministration of VEKLURY and chloroquine phosphate or hydroxychloroquine sulfate is not recommended based on in vitro data demonstrating an antagonistic effect of chloroquine on the intracellular metabolic activation and antiviral activity of VEKLURY.

Please see the following page for additional Important Information, and refer to the [Fact Sheet for Healthcare Providers](#) available at www.gilead.com/remdesivir.

IMPORTANT: VEKLURY must be administered intravenously. The optimal dosing and duration of VEKLURY for the treatment of COVID-19 is unknown. The suggested dose under this EUA is described in the [Fact Sheet for Healthcare Providers](#), available at www.gilead.com/remdesivir. The suggested dose and duration may be updated as data from clinical trials becomes available.

Authorized Use

VEKLURY® (remdesivir) is authorized for use under an EUA only for the treatment of adult and pediatric patients hospitalized with suspected or laboratory-confirmed COVID-19, and for whom use of an intravenous (IV) agent is clinically appropriate. VEKLURY must be administered via IV infusion.

Important Information (cont'd)

Patient monitoring:

Patients should have appropriate clinical and laboratory monitoring to aid in early detection of any potential adverse events. Monitor renal and hepatic function prior to initiating and daily during therapy with VEKLURY. The decision to continue or discontinue VEKLURY therapy after development of an adverse event should be made based on the clinical risk/benefit assessment for the individual patient. For additional information and mandatory adverse event reporting, please see the [Fact Sheet for Healthcare Providers](#).

Dosage and Administration

Adult and pediatric patients ≥ 40 kg:

- For patients requiring invasive mechanical ventilation and/or ECMO, the suggested dose is a single loading dose of VEKLURY (remdesivir) 200 mg on Day 1, followed by once-daily maintenance doses of VEKLURY (remdesivir) 100 mg for 9 days.
- For patients **not** requiring invasive mechanical ventilation and/or ECMO, the suggested dose is a single dose of VEKLURY (remdesivir) 200 mg on Day 1, followed by once-daily maintenance doses of VEKLURY (remdesivir) 100 mg for 4 days. If a patient does not demonstrate clinical improvement, treatment may be extended for up to 5 additional days (up to 10 days total).
- Administer VEKLURY (remdesivir) via intravenous infusion in a total volume of up to 250 mL 0.9% sodium chloride over 30 to 120 minutes.

Pediatric patients 3.5 kg to < 40 kg:

For pediatric patients with body weight between 3.5 kg and < 40 kg, only use VEKLURY (remdesivir) for injection, 100 mg, lyophilized powder. Refer to the [Fact Sheet for Healthcare Providers](#) for dosage and dose duration information for patients weighing < 40 kg.

Pregnancy:

VEKLURY should be used during pregnancy only if the potential benefit justifies the potential risk for the mother and the fetus.

Renal impairment:

VEKLURY is not recommended in adults and pediatric patients (> 28 days old) with an eGFR < 30 mL/min and in full-term neonates (≥ 7 days and ≤ 28 days old) with serum creatinine ≥ 1 mg/dL unless the potential benefit outweighs the potential risk. Prior to administration and daily during treatment with VEKLURY, all adult and pediatric patients (> 28 days old) must have an eGFR determined; full-term neonates (≥ 7 days to ≤ 28 days old) must have serum creatinine determined. Monitor renal function prior to initiating and daily during treatment with VEKLURY.

Hepatic impairment:

It is not known if dose adjustment is needed in patients with hepatic impairment, and VEKLURY should only be used in patients with hepatic impairment if the potential benefit outweighs the potential risk. Do not initiate VEKLURY in patients with ALT $\geq 5 \times$ ULN; discontinue therapy in patients who develop ALT $\geq 5 \times$ ULN or ALT elevation accompanied by signs or symptoms of liver inflammation or increasing conjugated bilirubin, alkaline phosphatase, or INR. Monitor hepatic function prior to initiating and daily during treatment with VEKLURY.

Drug interactions:

Drug interaction trials of VEKLURY and other concomitant medications have not been conducted in humans. Due to antagonism observed in vitro, concomitant use of VEKLURY with chloroquine phosphate or hydroxychloroquine sulfate is not recommended.

For more information, please refer to the [Fact Sheet for Healthcare Providers](#) available at www.gilead.com/remdesivir.

Reference: VEKLURY. EUA Fact Sheet. Foster City, CA: Gilead Sciences, Inc.; 2020.

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