Veklury® remdesivir 100 MG FOR INJECTION

VEKLURY® (remdesivir)

DOSING AND ADMINISTRATION GUIDE

VEKLURY® (remdesivir) for injection, 100 mg/vial, lyophilized powder

VEKLURY® (remdesivir) injection, 100 mg/20 mL (5 mg/mL), solution

INDICATION

VEKLURY is indicated for the treatment of adults and pediatric patients ≥12 years old and weighing ≥40 kg requiring hospitalization for COVID-19. VEKLURY should only be administered in a hospital or 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.

Please see last page for Important Safety Information and full Prescribing Information here.

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VEKLURY is available in two dosage forms, with the following appearances:

VEKLURY® (remdesivir) for injection, 100 mg/vial, lyophilized powder

- Sterile, preservative-free white to off-white to yellow powder (color does not affect product stability)
- Red cap on vial

Dose Preparation

VEKLURY for injection, 100 mg/vial, lyophilized powder **must be reconstituted with 19 mL Sterile Water for Injection and diluted in a 100 mL or 250 mL 0.9% sodium chloride infusion bag prior to administration.**

Please see pages 4-6 of the PDF for dose preparation instructions.

Administration

Diluted solution is administered intravenously by infusion for 30-120 minutes with the infusion rate described in TABLE 2 of the Prescribing Information.

Please see page 8 of the PDF for infusion rates and administration instructions.

VEKLURY® (remdesivir) injection, 100 mg/20 mL (5 mg/mL), solution

- Sterile, preservative-free, clear, colorless to yellow solution, free of visible particles
- Blue cap on vial

Dose Preparation

VEKLURY injection, 100 mg/20 mL (5 mg/mL), solution **must be diluted in a 250 mL 0.9% sodium chloride infusion bag prior to administration.**

Please see page 7 of the PDF for dose preparation instructions.

Administration

Only use the solution formulation for patients weighing at least 40 kg.

Diluted solution is administered intravenously by infusion for 30-120 minutes with the infusion rate described in TABLE 4 of the Prescribing Information.

Please see page 9 of the PDF for infusion rates and administration instructions.

Please see last page for Important Safety Information and full Prescribing Information here.

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DOSE RECONSTITUTION

VEKLURY® (remdesivir) for injection, 100 mg/vial, lyophilized powder

Remove the required number of single-dose vial(s) from storage. For each vial:

1. Aseptically reconstitute VEKLURY lyophilized powder by adding 19 mL of Sterile Water for Injection using a suitably sized syringe and needle per vial.
2. Only use Sterile Water for Injection to reconstitute VEKLURY lyophilized powder.
3. Discard the vial if a vacuum does not pull the Sterile Water for Injection into the vial.
4. Immediately shake the vial for 30 seconds.
5. Allow the contents of the vial to settle for 2 to 3 minutes. A clear solution should result.
6. 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. Discard the vial if the contents are not completely dissolved.
7. Following reconstitution, each vial contains 100 mg/20 mL (5 mg/mL) of remdesivir solution.
8. Use reconstituted product immediately to prepare the diluted drug product.

VEKLURY® (remdesivir) injection, 100 mg/20 mL (5 mg/mL), solution

Does not require reconstitution. See dilution instructions on page 7 of the PDF.

Please see last page for Important Safety Information and full Prescribing Information here.

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DILUTION

Care should be taken during admixture to prevent inadvertent microbial contamination. As there is no preservative or bacteriostatic agent present in this product, aseptic technique must be used in preparation of the final parenteral solution. It is always recommended to administer intravenous medication immediately after preparation when possible.

VEKLURY® (remdesivir) for injection, 100 mg/vial, lyophilized powder

Once the lyophilized powder has been reconstituted, it must be further diluted in either a 100 mL or 250 mL 0.9% sodium chloride infusion bag.

1. Withdraw and discard the required volume of 0.9% sodium chloride from the bag following instructions in **TABLE 1** below, using an appropriately sized syringe and needle.
2. Withdraw the required volume of reconstituted VEKLURY for injection from the VEKLURY vial following instructions in **TABLE 1** below, using an appropriately sized syringe. Discard any unused portion remaining in the reconstituted vial.
3. Transfer the required volume of reconstituted VEKLURY for injection to the selected infusion bag.
4. Gently invert the bag 20 times to mix the solution in the bag. Do not shake.
5. The prepared infusion solution is stable for 24 hours at room temperature (20 °C to 25 °C [68 °F to 77 °F]) or 48 hours at refrigerated temperature (2 °C to 8 °C [36 °F to 46 °F]).

Table 1 Recommended Dilution Instructions–Reconstituted VEKLURY for Injection Lyophilized Powder

VEKLURY 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 for injection
Loading dose 200 mg (2 vials)	250 mL	40 mL	40 mL (2 x 20 mL)
	100 mL		
Maintenance dose 100 mg (1 vial)	250 mL	20 mL	20 mL
	100 mL		

Please see last page for Important Safety Information and full Prescribing Information here.

VEKLURY® (remdesivir) injection, 100 mg/20 mL (5 mg/mL), solution

Remove the required number of single-dose vial(s) from storage. Each vial contains 100 mg/20 mL of remdesivir.

1. 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.
3. VEKLURY injection must be diluted in an infusion bag containing 250 mL of 0.9% sodium chloride only. Refer to **TABLE 2*** below for instructions.
4. Withdraw and discard the required volume of 0.9% sodium chloride from the bag following the instructions in **TABLE 2***, using an appropriately sized syringe and needle.
5. Withdraw the required volume of VEKLURY injection from the VEKLURY vial following instructions in **TABLE 2*** below, using an appropriately sized syringe and needle. Pull the syringe plunger rod back to fill the syringe with approximately 10 mL of air. Inject the air into the VEKLURY injection vial above the level of the solution. Invert the vial and withdraw the required volume of VEKLURY injection solution into the syringe. The last 5 mL of solution requires more force to withdraw.
6. Transfer the required volume of VEKLURY injection to the infusion bag.
7. Gently invert the bag 20 times to mix the solution in the bag. Do not shake.
8. The prepared infusion solution is stable for 24 hours at room temperature (20 °C to 25 °C [68 °F to 77 °F]) or 48 hours at refrigerated temperature (2 °C to 8 °C [36 °F to 46 °F]).

Table 2* Recommended Dilution Instructions—VEKLURY Injection (Supplied as Solution in Vial)

VEKLURY 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 injection
Loading dose 200 mg (2 vials)	250 mL	40 mL	40 mL (2 x 20 mL)
Maintenance dose 100 mg (1 vial)		20 mL	20 mL

*Table 3 in the VEKLURY Prescribing Information.

For both formulations, discard any unused solution remaining in the VEKLURY (remdesivir) vial. This product contains no preservative.

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ADMINISTRATION

Do not administer the prepared diluted solution simultaneously with any other medication. The compatibility of VEKLURY injection with intravenous solutions and medications other than 0.9% sodium chloride injection, USP is not known. Only administer VEKLURY via intravenous infusion over 30 to 120 minutes.

VEKLURY® (remdesivir) for injection, 100 mg/vial, lyophilized powder

Administer the diluted solution with the infusion rate described in **TABLE 3*** below.

Table 3* Recommended Rate of Infusion—Diluted VEKLURY for Injection Lyophilized Powder in Adults and Pediatric Patients 12 Years of Age and Older and Weighing at Least 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

*Table 2 in the VEKLURY Prescribing Information.

VEKLURY® (remdesivir) injection, 100 mg/20 mL (5 mg/mL), solution

Administer the diluted solution with the infusion rate described in **TABLE 4** below.

Table 4 Recommended Rate of Infusion—Diluted VEKLURY Injection Solution in Adults and Pediatric Patients 12 Years of Age and Older and Weighing at Least 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

VEKLURY is approved for use in adults and pediatric patients ≥12 years old and weighing ≥40 kg requiring hospitalization. For information about emergency use in hospitalized pediatric patients <12 years of age weighing ≥3.5 kg or weighing 3.5 kg to <40 kg, please see the EUA Fact Sheet and FDA Letter of Authorization available at gilead.com/remdesivir.

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INDICATION

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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 here.

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