

Remdesivir for Injection (100 mg) Lyophilized Powder

Remdesivir has been issued an Emergency Use Authorization (EUA) by the FDA for the treatment of coronavirus disease 2019 (COVID-19). Remdesivir is an investigational drug that has not been approved by the FDA for any use. It is not yet known if remdesivir is safe and effective for the treatment of COVID-19. The distribution of remdesivir has been authorized only for the treatment of hospitalized patients with severe COVID-19. For more information on the use of remdesivir, 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 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% saline to withdraw from the infusion bag.
- 8 Withdraw the required volume of saline from the bag using an appropriately sized syringe and needle. Discard the saline that was withdrawn from the bag.
- 9 Withdraw the required volume of reconstituted remdesivir for injection from the remdesivir vial using an appropriately sized syringe per **TABLE 1**. Discard any unused portion remaining in the remdesivir vial.
- 10 Transfer the required volume of reconstituted 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—Remdesivir for Injection Lyophilized Powder in Adults and Pediatric Patients Weighing ≥40 kg

Remdesivir dose	0.9% saline infusion bag volume to be used	Volume of saline to be withdrawn and discarded from 0.9% saline infusion bag	Required volume of reconstituted remdesivir for injection
200 mg (2 vials)	250 mL	40 mL	2 x 20 mL
	100 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 at least 30 mL of 0.9% saline.

TABLE 2. Recommended Rate of Infusion—Diluted 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 on pediatric patients (<40 kg), please refer to the [Fact Sheet for Healthcare Providers](#). Please see [Authorized Use and Important Information on pages 4-5](#).

Reference: Remdesivir [EUA Fact Sheet]. Foster City, CA: Gilead Sciences, Inc.; 2020.

IMPORTANT: Remdesivir must be administered intravenously. The optimal dosing and duration of remdesivir 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.

Remdesivir Injection (5 mg/mL) Concentrated 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% saline to withdraw from the infusion bag.
- 4 Withdraw the required volume of saline from the bag using an appropriately sized syringe and needle. Discard the saline that was withdrawn from the bag. Care should be taken during admixture to prevent inadvertent microbial contamination.
- 5 Withdraw the required volume of remdesivir injection solution from the 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 remdesivir injection vial above the level of the solution. Invert the vial and withdraw the required volume of remdesivir injection solution into the syringe. The last 5 mL of solution requires more force to withdraw. Discard any unused portion remaining in the remdesivir vial.
- 6 Transfer the required volume of 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 Remdesivir Solution Dilution Instructions in Adults and Pediatric Patients Weighing ≥40 kg

Remdesivir dose	0.9% saline infusion bag volume to be used	Volume of saline to be withdrawn and discarded from 0.9% saline infusion bag	Required volume of remdesivir injection solution
200 mg (2 vials)	250 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 at least 30 mL of 0.9% saline.

TABLE 4. Recommended Rate of Infusion for Diluted 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 on pediatric patients (<40 kg), please refer to the [Fact Sheet for Healthcare Providers](http://www.gilead.com/remdesivir). Please see [Authorized Use and Important Information on pages 4-5](#).

Reference: Remdesivir [EUA Fact Sheet]. Foster City, CA: Gilead Sciences, Inc.; 2020.

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

Frequently Asked Questions

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

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

Remdesivir (GS-5734™) is authorized for use under an EUA only for the treatment of patients with suspected or laboratory-confirmed SARS-CoV-2 infection and severe COVID-19. Severe disease is defined as patients with an oxygen saturation (SpO₂) ≤94% on room air or requiring supplemental oxygen, mechanical ventilation, and/or extracorporeal membrane oxygenation (ECMO). Remdesivir is authorized for adult or pediatric patients who are admitted to a hospital and for whom use of an IV agent is clinically appropriate. Remdesivir must be administered intravenously. See the [Fact Sheet for Healthcare Providers](#) for additional information on the storage, handling, preparation, and administration of remdesivir IV solution.

What is the product description for remdesivir?

Lyophilized Powder

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 diluted into 0.9% saline prior to administration by intravenous (IV) infusion. Following reconstitution, each vial contains 5 mg/mL remdesivir reconstituted solution with sufficient volume to allow withdrawal of 20 mL of 5 mg/mL solution containing 100 mg of remdesivir. 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. 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. The container closure is not made with natural rubber latex.

Injection Solution

Remdesivir injection, 5 mg/mL, is a sterile, preservative-free, clear, colorless to yellow, aqueous-based concentrated solution that is to be diluted into 0.9% saline prior to administration by IV infusion. Each vial contains sufficient volume to allow withdrawal of 20 mL of 5 mg/mL solution containing 100 mg of remdesivir. Remdesivir injection, 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 remdesivir be stored prior to use?

Lyophilized Powder

Store 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 remdesivir injection, 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 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 remdesivir be reused?

Do not reuse or save unused 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 remdesivir. For unused intact vials, maintain adequate records showing disposition of remdesivir; do not discard unused intact vials.

Is 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 remdesivir injection with IV solutions and medications other than 0.9% saline is not known. Remdesivir for injection (100 mg lyophilized powder) must be reconstituted with Sterile Water for Injection and diluted in 0.9% saline. Remdesivir injection (5 mg/mL solution) must be diluted in 0.9% saline.

Am I required to report adverse events for 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 remdesivir treatment and considered to be potentially attributable to remdesivir. 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.

Reference: Remdesivir [EUA Fact Sheet]. Foster City, CA: Gilead Sciences, Inc.; 2020.

IMPORTANT: Remdesivir must be administered intravenously. The optimal dosing and duration of remdesivir 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

Remdesivir (GS-5734™) is authorized for use under an EUA only for the treatment of patients with suspected or laboratory-confirmed SARS-CoV-2 infection and severe COVID-19. Severe disease is defined as patients with an oxygen saturation (SpO₂) ≤94% on room air or requiring supplemental oxygen, mechanical ventilation, and/or extracorporeal membrane oxygenation (ECMO). Remdesivir is authorized for adult or pediatric patients who are admitted to a hospital and for whom use of an IV agent is clinically appropriate. Remdesivir must be administered intravenously.

Important Information

The Secretary of the Department of Health and Human Services has declared a public health emergency that justifies the emergency use of remdesivir 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, remdesivir, for the treatment of COVID-19.

- Remdesivir is an investigational drug that has not been approved by the FDA for any use. It is not yet known if remdesivir is safe and effective for the treatment of COVID-19.
- The distribution of remdesivir has been authorized only for the treatment of hospitalized patients with severe COVID-19. It is not authorized for the treatment of any other viruses or pathogens.
- 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 remdesivir and mandatory requirements of the EUA.
- Remdesivir 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 remdesivir treatment and considered to be potentially attributable to remdesivir. 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.
- For information about clinical trials that are testing the use of remdesivir for the treatment of COVID-19, please see www.clinicaltrials.gov.

Overall Safety Summary

Remdesivir 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 remdesivir use.

Warnings: In clinical studies with remdesivir, infusion-related reactions and liver transaminase elevations have been observed. Remdesivir should not be used in patients who are hypersensitive to any ingredient of remdesivir. If signs and symptoms of a clinically significant infusion reaction occur, immediately discontinue administration of remdesivir and initiate appropriate treatment. Do not initiate remdesivir in patients with ALT ≥5x ULN; discontinue therapy in patients who develop ALT ≥5x ULN or ALT elevation accompanied by signs or symptoms of liver inflammation or increasing conjugated bilirubin, alkaline phosphatase, or INR.

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 remdesivir; additionally monitor serum chemistries and hematology daily during therapy. The decision to continue or discontinue remdesivir 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](#).

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

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Important Information (cont'd)

Dosing and Administration:

Adult Patients:

- For patients requiring invasive mechanical ventilation and/or ECMO, the suggested dose is a single loading dose of remdesivir 200 mg on Day 1, followed by once-daily maintenance doses of remdesivir 100 mg for 9 days.
- For patients not requiring invasive mechanical ventilation and/or ECMO, the suggested dose is a single dose of remdesivir 200 mg on Day 1, followed by once-daily maintenance doses of 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).
- Remdesivir is to be administered via intravenous infusion in a total volume of up to 250 mL 0.9% saline over 30 to 120 minutes.

Pediatric Patients:

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

Pregnancy:

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

Renal impairment:

Remdesivir 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. All adult and pediatric patients (>28 days old) must have an eGFR determined before dosing; full-term neonates (≥7 days to ≤28 days old) must have serum creatinine determined before dosing. Monitor renal function prior to initiating and daily during treatment with remdesivir.

Hepatic impairment:

It is not known if dose adjustment is needed in patients with hepatic impairment, and remdesivir should only be used in patients with hepatic impairment if the potential benefit outweighs the potential risk. Do not initiate remdesivir in patients with ALT ≥5x ULN; discontinue therapy in patients who develop ALT ≥5x 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 remdesivir.

Drug interactions:

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

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

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