

## **Remdesivir**

### **Trade Name(s)**

Veklury

### **Formulation**

Provided as two different formulations of remdesivir: a lyophilized powder for injection and a concentrated injection solution.

Lyophilized powder for injection:

Provided as a sterile, preservative-free, white to off-white to yellow, lyophilized powder in single-dose vials containing remdesivir 100 mg with betadex sulfobutyl ether sodium 3 g. Hydrochloric acid and/or sodium hydroxide may have been added during manufacturing for pH adjustment.

Concentrated injection solution:

Provided as a sterile, preservative-free, clear, colorless to yellow, aqueous-based solution in single-dose vials containing remdesivir 100 mg/20 mL (5 mg/mL) with betadex sulfobutyl ether sodium 6 g in water for injection. Hydrochloric acid and/or sodium hydroxide may have been added during manufacturing for pH adjustment.

NOTE: In October 2020, the FDA approved remdesivir (Veklury) for the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adult and pediatric patients (at least 12 years of age and weighing at least 40 kg). The emergency use authorization (EUA) issued by the FDA in May 2020 continues to allow for remdesivir to be used by licensed healthcare providers for the treatment of suspected or laboratory-confirmed COVID-19 in hospitalized pediatric patients weighing at least 3.5 kg.

The excipient betadex sulfobutyl ether sodium (also referred to as sulfobutylether-beta-cyclodextrin sodium salt [SBECD]) is renally cleared and accumulates in patients with decreased renal function. Based on the lower content of this excipient and resulting lower tonicity in the lyophilized powder as compared to the concentrated injection solution, the EUA Fact Sheet for Healthcare Providers recommends use of only the lyophilized powder for injection in pediatric patients weighing less than 40 kg.<sup>Ref</sup>

### **Reconstitution**

Lyophilized powder for injection:

Reconstitute vial with 19 mL SWFI; shake for 30 seconds. Allow vial contents to settle for 2 to 3 minutes; if not completely dissolved, repeat process as necessary until vial contents are completely dissolved. Reconstituted vial contains 100 mg per 20 mL (5 mg/mL). Further dilution in NS is required prior to administration.

Patients weighing 40 kg or more:

Dilute in NS to a final volume of 100 or 250 mL; withdraw and discard the required volume of NS from the infusion bag (40 mL for a 200 mg dose; 20 mL for a 100 mg dose) prior to addition of remdesivir. Transfer required volume of remdesivir to the infusion bag and gently invert 20 times to mix the solution; do not shake. Discard unused portion of the reconstituted vial.

Patients weighing 3.5 to < 40 kg:

Volume of NS to be used is based on patient weight and type of dose (eg, loading dose, maintenance dose). If using infusion bags, withdraw and discard a volume of NS equal to the volume of remdesivir dose from infusion bag prior to addition of remdesivir (unless dose volume < 2.5 mL). Following transfer of remdesivir to NS, gently invert 20 times to mix the solution; do not shake. Final total volume of infusion is as follows:

Loading dose:

17.5 to 25 mg - 25 mL total volume of infusion

> 25 mg to 50 mg - 50 mL total volume of infusion

> 50 mg to 150 mg - 100 mL total volume of infusion

> 150 mg - 250 mL total volume of infusion

Maintenance dose:

8.8 to 12.5 mg - 25 mL total volume of infusion

> 12.5 to 50 mg - 50 mL total volume of infusion

> 50 mg - 100 mL total volume of infusion

Concentrated injection solution:

Patients weighing 40 kg or more:

Allow injection solution vial(s) to warm to room temperature prior to dilution. Further dilute in NS to a final volume of 250 mL; withdraw and discard the required volume of NS from the infusion bag (40 mL for a 200 mg dose; 20 mL for a 100 mg dose) prior to addition of remdesivir. Transfer required volume of remdesivir to the infusion bag and gently invert 20 times to mix the solution; do not shake. Discard unused portion of the injection solution vial.

Patients weighing 3.5 to < 40 kg:

Concentrated injection solution should not be used. The EUA Fact Sheet for Healthcare Providers recommends use of only the lyophilized powder in pediatric patients weighing less than 40 kg (see Formulation).

NOTE: The recommendation to remove and discard a volume of NS equivalent to the volume of remdesivir prior to the addition of remdesivir is a precaution to ensure there is sufficient head-space in the IV bag. If it is known that there is sufficient head-space in the IV bag, then the step to remove NS prior to remdesivir addition may be omitted. <sup>Ref</sup>

### **Stability**

Lyophilized powder:

After reconstitution, use vials immediately to prepare diluted solution. Once diluted for infusion, may store at 20°C to 25°C (68°F to 77°F) for 24 hours or refrigerated at 2°C to 8°C (36°F to 46°F) for 48 hours. Discard unused portion of the reconstituted vial.

Concentrated injection solution:

Once diluted for infusion, may store at 20°C to 25°C (68°F to 77°F) for 24 hours or refrigerated at 2°C to 8°C (36°F to 46°F) for 48 hours. Discard unused portion of the injection solution vial. <sup>Ref</sup>

### **Storage**

Lyophilized powder:

Store intact vials under 30°C (under 86°F).

Concentrated injection solution:

Store intact vials refrigerated at 2°C to 8°C (36°F to 46°F). Prior to dilution, allow vials to warm to room temperature; intact vials can be stored up to 12 hours at room temperature prior to dilution. <sup>Ref</sup>

### **Sorption**

The manufacturer recommends dilution in an infusion bag without specifying the plastic composition. <sup>Ref</sup>

### **Other Information**

The manufacturer states that remdesivir should not be administered as an infusion with any other drugs. <sup>Ref</sup>

### **Citations**

Anon, "US Food and Drug Administration. Fact Sheet For Health Care Providers Emergency Use Authorization (EUA) of Veklury (remdesivir). <https://www.fda.gov/media/137566/download>", Gilead Sciences, 2020.

Anon, "Veklury (remdesivir) [prescribing information]", Foster City, CA: Gilead Sciences, Inc, 2020.

Institute for Safe Medication Practices (ISMP), "Reported medication errors with Veklury (remdesivir) Emergency Use Authorization", ISMP Medication Safety Alert! Acute Care Edition, 2020; Volume 25: pp. 1-2.

Anon, "Veklury (remdesivir) - Overfill During Dose Preparation", Gilead Sciences, Inc: Data on File, 2020.



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