Trissel's™ 2 Clinical Pharmaceutics Database (created by Lawrence A. Trissel)

Remdesivir

Formulation

In May 2020, the FDA issued an emergency use authorization for remdesivir, an investigational agent, to be distributed in the United States to treat suspected or laboratory-confirmed COVID-19 in patients hospitalized with severe disease.

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, white to off-white to yellow, preservative-free lyophilized powder in single-dose vials containing remdesivir 100 mg with sulfobutylether-beta-cyclodextrin sodium salt (SBECD) 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 5 mg/mL with SBECD 6 g. Hydrochloric acid and/or sodium hydroxide may have been added during manufacturing for pH adjustment. [Ref]

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.

For patients weighing 40 kg or more, dilute in 100 or 250 mL NS; 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.

For patients weighing less than 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 total 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. [Ref]

Stability

Lyophilized powder:
After reconstitution, vials may be stored at 20°C to 25°C (68°F to 77°F) for up to 4 hours or refrigerated at 2°C to 8°C (36°F to 46°F) for up to 24 hours prior to administration. Once diluted for infusion, may store at 20°C to 25°C (68°F to 77°F) for up to 4 hours or refrigerated at 2°C to 8°C (36°F to 46°F) for up to 24 hours.

Concentrated injection solution:
Once diluted for infusion, may store at 20°C to 25°C (68°F to 77°F) for up to 4 hours or refrigerated at 2°C to 8°C (36°F to 46°F) for up to 24 hours. Ref

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. Ref

Sorption

The manufacturer recommends dilution in an infusion bag without specifying the plastic composition. Ref

Other Information

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

Citations

Anon, "US Food and Drug Administration. Fact Sheet For Health Care Providers Emergency Use Authorization (EUA) of Remdesivir (GS-5734). https://www.fda.gov/media/137566/download", Gilead Sciences, 2020.