Remdesivir

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Remdesivir is a nucleotide prodrug of an adenosine analog. It binds to the viral RNA-dependent RNA polymerase and inhibits viral replication by terminating RNA transcription prematurely. Remdesivir has demonstrated in vitro and in vivo activity against SARS-CoV-2.¹

Intravenous remdesivir is approved by the Food and Drug Administration (FDA) for the treatment of COVID-19 in adults and pediatric patients aged ≥28 days and weighing ≥3 kg. In nonhospitalized patients with mild to moderate COVID-19 who are at high risk of progressing to severe disease, remdesivir should be started within 7 days of symptom onset and administered for 3 days. Hospitalized patients should receive remdesivir for 5 days or until hospital discharge, whichever comes first.² The FDA prescribing information for remdesivir indicates that if a patient does not clinically improve within 5 days, clinicians may extend the treatment course for up to 5 additional days (for a total duration of 10 days). See Table 4e for more information on administering remdesivir.

Remdesivir has been studied in several clinical trials for the treatment of COVID-19. The recommendations from the COVID-19 Treatment Guidelines Panel (the Panel) are based on the results of these studies. See Table 4a for more information.

Recommendations

- For the Panel’s recommendations and information on the clinical efficacy of using remdesivir to treat high-risk, nonhospitalized patients with mild to moderate COVID-19, see Therapeutic Management of Nonhospitalized Adults With COVID-19.
- For the Panel’s recommendations and information on the clinical efficacy of using remdesivir with or without immunomodulators to treat certain hospitalized patients, see Therapeutic Management of Hospitalized Adults With COVID-19.

Monitoring, Adverse Effects, and Drug-Drug Interactions

Remdesivir can cause gastrointestinal symptoms (e.g., nausea), elevated transaminase levels, an increase in prothrombin time without a change in the international normalized ratio, and hypersensitivity reactions. Bradycardia has also been reported.³,⁴

The FDA approved remdesivir for use without dose adjustment in patients with an estimated glomerular filtration rate (eGFR) of <30 mL/min, including those receiving dialysis.³ Remdesivir is formulated with sulfobutylether-beta-cyclodextrin (SBECD) sodium. SBECD is a vehicle that is primarily eliminated through the kidneys. Accumulation of SBECD in patients with renal impairment may result in liver and renal toxicities. The REDPINE trial evaluated the use of remdesivir for 5 days in patients with COVID-19 and an eGFR of <30 mL/min, and a Phase 1 trial evaluated the use of a single dose of remdesivir in individuals with different degrees of renal impairment. Neither trial reported significant safety concerns.

Before starting patients on remdesivir, the FDA recommends performing liver function and prothrombin time tests as clinically appropriate and repeating these tests during treatment as clinically indicated. Remdesivir may need to be discontinued if a patient’s alanine transaminase level increases to >10 times the upper limit of normal, and it should be discontinued if increases in alanine transaminase levels and signs or symptoms of liver inflammation are observed.²
Remdesivir should be administered in a setting where severe hypersensitivity reactions, such as anaphylaxis, can be managed. Patients should be monitored during the infusion and observed for at least 1 hour after the infusion as clinically appropriate.

No clinically significant drug-drug interactions are expected with cytochrome P450 3A4 inducers or with inhibitors of P-glycoprotein or organic anion transporting polypeptides 1B1 or 1B3.2 See Table 4e for more information.

Patients Who Are Immunocompromised and Have Prolonged Symptoms and Evidence of Ongoing Viral Replication

Patients who are severely immunocompromised may have a prolonged duration of SARS-CoV-2 replication, which may lead to rapid viral evolution. There is concern that using a single antiviral agent in these patients may result in the emergence of resistant virus.5 Additional studies are needed to assess this risk. The data on using combinations of antiviral therapies for the treatment of COVID-19 are limited.6 Clinical trials are needed to determine the role of combination therapy in treating patients with COVID-19.

For patients who are immunocompromised and have prolonged COVID-19 symptoms and evidence of ongoing viral replication (e.g., those with a low cycle threshold value, as measured by a reverse transcription polymerase chain reaction result or with a positive rapid antigen test result) despite receiving a course of antiviral therapy, the optimal management is unknown. Case reports and case series have documented treating these patients with additional antiviral treatments, prolonged courses of antiviral treatments, high-titer COVID-19 convalescent plasma, or combination therapy.7-11

For more information on the use of remdesivir in patients who are moderately to severely immunocompromised, see Special Considerations in People Who Are Immunocompromised, Therapeutic Management of Hospitalized Adults With COVID-19, and Therapeutic Management of Nonhospitalized Adults With COVID-19.

Considerations in Pregnant and Lactating People

See Pregnancy, Lactation, and COVID-19 Therapeutics for the Panel’s guidance regarding the use of remdesivir during pregnancy and lactation.

Considerations in Children


References


