

Remdesivir

Last Updated: February 29, 2024

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.² 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

See [Therapeutic Management of Nonhospitalized Children With COVID-19](#) and [Therapeutic Management of Hospitalized Children With COVID-19](#) for the Panel's guidance regarding the use of remdesivir in children.

References

1. Wang M, Cao R, Zhang L, et al. Remdesivir and chloroquine effectively inhibit the recently emerged novel coronavirus (2019-nCoV) in vitro. *Cell Res*. 2020;30(3):269-271. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/32020029>.
2. Remdesivir (Veklury) [package insert]. Food and Drug Administration. 2023. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/214787s019lbl.pdf.
3. Devgun JM, Zhang R, Brent J, et al. Identification of bradycardia following remdesivir administration through the US Food and Drug Administration American College of Medical Toxicology COVID-19 Toxic Pharmacovigilance Project. *JAMA Netw Open*. 2023;6(2):e2255815. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/36787141>.

4. Ishisaka Y, Aikawa T, Malik A, et al. Association of remdesivir use with bradycardia: a systematic review and meta-analysis. *J Med Virol.* 2023;95(8):e29018. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/37539782>.
5. Gandhi S, Klein J, Robertson AJ, et al. De novo emergence of a remdesivir resistance mutation during treatment of persistent SARS-CoV-2 infection in an immunocompromised patient: a case report. *Nat Commun.* 2022;13(1):1547. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/35301314>.
6. Gliga S, Lübke N, Killer A, et al. Rapid selection of sotrovimab escape variants in severe acute respiratory syndrome coronavirus 2 Omicron-infected immunocompromised patients. *Clin Infect Dis.* 2023;76(3):408-415. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/36189631>.
7. Huygens S, Gharbharan A, Serroukh Y, et al. High-titer convalescent plasma plus nirmatrelvir/ritonavir treatment for non-resolving COVID-19 in six immunocompromised patients. *J Antimicrob Chemother.* 2023;78(7):1644-1648. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/37248664>.
8. Brosh-Nissimov T, Ma'aravi N, Leshin-Carmel D, et al. Combination treatment of persistent COVID-19 in immunocompromised patients with remdesivir, nirmatrelvir/ritonavir and tixagevimab/cilgavimab. *J Microbiol Immunol Infect.* 2023;S1684-1182(23):00170-6. Available at: <https://pubmed.ncbi.nlm.nih.gov/37805361>.
9. Mikulska M, Sepulcri C, Dentone C, et al. Triple combination therapy with two antivirals and monoclonal antibodies for persistent or relapsed SARS-CoV-2 infection in immunocompromised patients. *Clin Infect Dis.* 2023;77(2):280-286. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/36976301>.
10. Graziani L, Gori L, Manciuilli T, et al. Successful use of nirmatrelvir/ritonavir in immunocompromised patients with persistent and/or relapsing COVID-19. *J Antimicrob Chemother.* 2023;78(2):555-558. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/36544352>.
11. Trottier CA, Wong B, Kohli R, et al. Dual antiviral therapy for persistent coronavirus disease 2019 and associated organizing pneumonia in an immunocompromised host. *Clin Infect Dis.* 2023;76(5):923-925. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/36281907>.