

## Remdesivir: COVID-19 Treatment Guidelines.

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Remdesivir, sold under the brand name Veklury is a broad-spectrum antiviral medication developed by the biopharmaceutical company Gilead Sciences. It is administered via injection into a vein. During the COVID-19 pandemic, remdesivir was approved or authorized for emergency use to treat COVID-19 in around 50 countries. Updated guidelines from the World Health Organization in November 2020 include a conditional recommendation against the use of remdesivir for the treatment of COVID-19.

Remdesivir is an intravenous nucleotide prodrug of an adenosine analog. Remdesivir binds to the viral RNA-dependent RNA polymerase and inhibits viral replication through premature termination of RNA transcription. It has demonstrated *in vitro* activity against SARS-CoV-2. In a rhesus macaque model of SARS-CoV-2 infection, remdesivir treatment was initiated soon after inoculation; the remdesivir-treated animals had lower virus levels in the lungs and less lung damage than the control animals.

Remdesivir is approved by the Food and Drug Administration (FDA) for the treatment of COVID-19 in hospitalized adult and pediatric patients (aged  $\geq 12$  years and weighing  $\geq 40$  kg). It is also available through an FDA Emergency Use Authorization (EUA) for the treatment of COVID-19 in hospitalized pediatric patients weighing 3.5 kg to  $< 40$  kg or aged  $< 12$  years and weighing  $\geq 3.5$  kg. Remdesivir should be administered in a hospital or a health care setting that can provide a similar level of care to an inpatient hospital.

### Monitoring and Adverse Effects

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.

Liver function tests and prothrombin time should be obtained in all patients before remdesivir is administered and during treatment as clinically indicated. Remdesivir may need to be discontinued if alanine transaminase (ALT) levels increase to  $> 10$  times the upper limit of normal and should be discontinued

if an increase in ALT level and signs or symptoms of liver inflammation are observed.

### Considerations

Pregnant patients were excluded from the clinical trials that evaluated the safety and efficacy of remdesivir for the treatment of COVID-19, but preliminary reports of remdesivir use in pregnant patients from the remdesivir compassionate use program are reassuring. Among 86 pregnant and postpartum hospitalized patients with severe COVID-19 who received compassionate use remdesivir, the therapy was well tolerated, with a low rate of serious adverse events.

Remdesivir should not be withheld from pregnant patients if it is otherwise indicated. The safety and effectiveness of using remdesivir to treat COVID-19 have not been evaluated in pediatric patients aged  $< 12$  years or weighing  $< 40$  kg. Remdesivir is available through an FDA EUA for the treatment of COVID-19 in hospitalized pediatric patients weighing 3.5 kg to  $< 40$  kg or aged  $< 12$  years and weighing  $\geq 3.5$  kg.

A clinical trial is currently evaluating the pharmacokinetics of remdesivir in children. Minimal to no reduction in remdesivir exposure is expected when remdesivir is co-administered with dexamethasone, according to information provided by Gilead Sciences (written communication, July 2020). Chloroquine or hydroxychloroquine may decrease the antiviral activity of remdesivir; co-administration of these drugs is not recommended.

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