

# Table 2e. Characteristics of Antiviral Agents That Are Approved or Under Evaluation for the Treatment of COVID-19

Last Updated: July 08, 2021

<p><b>Dosing Regimens</b></p> <p><i>The doses listed here are for approved indications or from reported experiences or clinical trials.</i></p>	<p><b>Adverse Events</b></p>	<p><b>Monitoring Parameters</b></p>	<p><b>Drug-Drug Interaction Potential</b></p>	<p><b>Comments and Links to Clinical Trials</b></p>
<p><b>Remdesivir</b></p>				
<p>The doses and indications listed below come from the FDA product information. Please see <a href="#">Therapeutic Management of Hospitalized Adults With COVID-19</a> for the Panel's recommendations on when to use RDV.</p> <p><b>For Hospitalized Adults and Children (Aged ≥12 Years and Weighing ≥40 kg)</b></p> <p><i>For Patients Who Are Not Mechanically Ventilated and/or on ECMO:</i></p> <ul style="list-style-type: none"> <li>• RDV 200 mg IV<sup>a</sup> on Day 1, then RDV 100 mg IV on Days 2–5</li> <li>• For patients who do not show clinical improvement after 5 days of therapy, treatment may be extended to up to 10 days.</li> </ul> <p><i>For Mechanically Ventilated Patients and/or Patients on ECMO:</i></p> <ul style="list-style-type: none"> <li>• RDV 200 mg IV<sup>a</sup> on Day 1, then RDV 100 mg IV on Days 2–10</li> </ul> <p><b>Suggested Dose in EUA<sup>b</sup> for Hospitalized Children</b></p> <p><i>For Patients Weighing 3.5 kg to &lt;40 kg:</i></p> <ul style="list-style-type: none"> <li>• RDV 5 mg/kg IV<sup>a</sup> on Day 1, then RDV 2.5 mg/kg IV once daily starting on Day 2</li> </ul>	<ul style="list-style-type: none"> <li>• Nausea</li> <li>• ALT and AST elevations</li> <li>• Hypersensitivity</li> <li>• Increases in prothrombin time</li> <li>• Drug vehicle is SBECD, which has been associated with renal and liver toxicity. SBECD accumulation may occur in patients with moderate or severe renal impairment.</li> <li>• Each 100 mg vial of RDV lyophilized powder contains 3 g of SBECD, and each 100 mg/20 mL vial of RDV solution contains 6 g of SBECD.</li> <li>• Clinicians may consider preferentially using the lyophilized powder formulation (which contains less SBECD) in patients with renal impairment.</li> </ul>	<ul style="list-style-type: none"> <li>• Infusion reactions</li> <li>• Renal function and hepatic function should be monitored before and during treatment as clinically indicated.</li> <li>• In the FDA product information, RDV <b>is not recommended</b> when eGFR is &lt;30 mL/min. See the <a href="#">Remdesivir</a> section for a discussion on using RDV in people with renal insufficiency.</li> <li>• RDV may need to be discontinued if ALT level increases to &gt;10 times ULN and should be discontinued if there is an increase in ALT level and signs or symptoms of liver inflammation are observed.<sup>1</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Clinical drug-drug interaction studies of RDV have not been conducted.</li> <li>• In vitro, RDV is a substrate of CYP3A4, OATP1B1, and P-gp and an inhibitor of CYP3A4, OATP1B1, OATP1B3, and MATE1.<sup>1</sup></li> <li>• Minimal to no reduction in RDV exposure is expected when RDV is coadministered with dexamethasone (Gilead Sciences, written communication, July 2020).</li> <li>• CQ or HCQ may decrease the antiviral activity of RDV; coadministration of these drugs <b>is not recommended</b>.<sup>1</sup></li> <li>• No significant interaction is expected between RDV and oseltamivir or baloxavir (Gilead Sciences, personal and written communications, August and September 2020).</li> </ul>	<ul style="list-style-type: none"> <li>• RDV should be administered in a hospital or a health care setting that can provide a similar level of care to an inpatient hospital.</li> <li>• RDV is approved by the FDA for the treatment of COVID-19 in hospitalized adult and pediatric patients (aged ≥12 years and weighing ≥40 kg).</li> <li>• An EUA<sup>b</sup> is available for hospitalized pediatric patients weighing 3.5 kg to &lt;40 kg or aged &lt;12 years and weighing ≥3.5 kg.</li> <li>• A list of clinical trials is available here: <a href="#">Remdesivir</a></li> </ul>

<b>Dosing Regimens</b> <i>The doses listed here are for approved indications or from reported experiences or clinical trials.</i>	<b>Adverse Events</b>	<b>Monitoring Parameters</b>	<b>Drug-Drug Interaction Potential</b>	<b>Comments and Links to Clinical Trials</b>
<ul style="list-style-type: none"> <li>For patients who are not mechanically ventilated and/or on ECMO, the duration is 5 days. If patients have not shown clinical improvement after 5 days, treatment may be extended to up to 10 days.</li> <li>For mechanically ventilated patients and/or patients on ECMO, the recommended treatment duration is 10 days.</li> </ul> <p><i>For Patients Aged &lt;12 Years and Weighing ≥40 kg:</i></p> <ul style="list-style-type: none"> <li>Same dose as for adults</li> </ul>				
<b>Ivermectin</b>				
<b>Adults:</b> <ul style="list-style-type: none"> <li>The dose most commonly used in clinical trials is IVM 0.2–0.6 mg/kg PO given as a single dose or as a once-daily dose for up to 5 days.</li> </ul>	<ul style="list-style-type: none"> <li>Generally well tolerated</li> <li>Dizziness</li> <li>Pruritis</li> <li>GI effects (e.g., nausea, diarrhea)</li> <li>Neurological AEs have been reported when IVM has been used to treat parasitic diseases, but it is not clear whether these AEs were caused by IVM or the underlying conditions.</li> </ul>	<ul style="list-style-type: none"> <li>Monitor for potential AEs.</li> </ul>	<ul style="list-style-type: none"> <li>Minor CYP3A4 substrate</li> <li>P-gp substrate</li> </ul>	<ul style="list-style-type: none"> <li>Generally given on an empty stomach with water; however, administering IVM with food increases its bioavailability.<sup>2</sup></li> <li>A list of clinical trials is available here: <a href="#">Ivermectin</a></li> </ul>
<b>Nitazoxanide</b>				

<b>Dosing Regimens</b> <i>The doses listed here are for approved indications or from reported experiences or clinical trials.</i>	<b>Adverse Events</b>	<b>Monitoring Parameters</b>	<b>Drug-Drug Interaction Potential</b>	<b>Comments and Links to Clinical Trials</b>
<b>Adults:</b> <ul style="list-style-type: none"> <li>Doses reported in COVID-19 studies range from NTZ 500 mg PO 3 times daily to 4 times daily.<sup>3,4</sup> Higher doses are being studied (<i>ClinicalTrials.gov</i> Identifier <a href="https://clinicaltrials.gov/ct2/show/study/NCT04746183">NCT04746183</a>).</li> <li>Doses used for antiprotozoal indications range from NTZ 500 mg to 1 g PO twice daily.</li> </ul>	<ul style="list-style-type: none"> <li>Generally well tolerated</li> <li>Abdominal pain</li> <li>Diarrhea</li> <li>Headache</li> <li>Nausea</li> <li>Vomiting</li> <li>Urine discoloration</li> <li>Ocular discoloration (rare)</li> </ul>	<ul style="list-style-type: none"> <li>Monitor for potential AEs.</li> </ul>	<ul style="list-style-type: none"> <li>Drug-drug interactions may occur if NTZ is administered concurrently with other highly plasma protein-bound drugs due to competition for binding sites.<sup>5</sup></li> <li>If NTZ is coadministered with other highly protein-bound drugs with narrow therapeutic indices, monitor the patient for AEs.</li> </ul>	<ul style="list-style-type: none"> <li>NTZ should be taken with food.</li> <li>The oral suspension is not bioequivalent to the tablet formulation.</li> <li>A list of clinical trials is available here: <a href="#">Nitazoxanide</a></li> </ul>

<sup>a</sup> Infuse over 30–120 minutes.

<sup>b</sup> The FDA EUA permits the emergency use of RDV for the treatment of suspected COVID-19 or laboratory-confirmed SARS-CoV-2 infection in hospitalized pediatric patients weighing 3.5 kg to <40 kg or aged <12 years and weighing ≥3.5 kg.<sup>6</sup>

**Key:** AE = adverse event; ALT = alanine transaminase; AST = aspartate aminotransferase; CQ = chloroquine; CYP = cytochrome P450; ECMO = extracorporeal membrane oxygenation; eGFR = estimated glomerular filtration rate; EUA = Emergency Use Authorization; FDA = Food and Drug Administration; GI = gastrointestinal; HCQ = hydroxychloroquine; IV = intravenous; IVM = ivermectin; LPV/RTV = lopinavir/ritonavir; MATE = multidrug and toxin extrusion protein; NTZ = nitazoxanide; OATP = organic anion transporter polypeptide; the Panel = the COVID-19 Treatment Guidelines Panel; P-gp = P-glycoprotein; PO = orally; RDV = remdesivir; SBECD = sulfobutylether-beta-cyclodextrin; ULN = upper limit of normal



[www.covid19treatmentguidelines.nih.gov](http://www.covid19treatmentguidelines.nih.gov)

An official website of the [National Institutes of Health](#)