

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

Last Updated: July 08, 2021

Dosing Regimens <i>The doses listed here are for approved indications or from reported experiences or clinical trials.</i>	Adverse Events	Monitoring Parameters	Drug-Drug Interaction Potential	Comments and Links to Clinical Trials
Remdesivir				

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

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<ul style="list-style-type: none"> 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. For mechanically ventilated patients and/or patients on ECMO, the recommended treatment duration is 10 days. <p><i>For Patients Aged <12 Years and Weighing ≥40 kg:</i></p> <ul style="list-style-type: none"> Same dose as for adults 				

Ivermectin

<p>Adults:</p> <ul style="list-style-type: none"> 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. 	<ul style="list-style-type: none"> Generally well tolerated Dizziness Pruritis GI effects (e.g., nausea, diarrhea) 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. 	<ul style="list-style-type: none"> Monitor for potential AEs. 	<ul style="list-style-type: none"> Minor CYP3A4 substrate P-gp substrate 	<ul style="list-style-type: none"> Generally given on an empty stomach with water; however, administering IVM with food increases its bioavailability.² A list of clinical trials is available here: Ivermectin
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Nitazoxanide

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<p>Adults:</p> <ul style="list-style-type: none"> • Doses reported in COVID-19 studies range from NTZ 500 mg PO 3 times daily to 4 times daily.^{3,4} Higher doses are being studied (<i>ClinicalTrials.gov</i> Identifier NCT04746183). • Doses used for antiprotozoal indications range from NTZ 500 mg to 1 g PO twice daily. 	<ul style="list-style-type: none"> • Generally well tolerated • Abdominal pain • Diarrhea • Headache • Nausea • Vomiting • Urine discoloration • Ocular discoloration (rare) 	<ul style="list-style-type: none"> • Monitor for potential AEs. 	<ul style="list-style-type: none"> • Drug-drug interactions may occur if NTZ is administered concurrently with other highly plasma protein-bound drugs due to competition for binding sites.⁵ • If NTZ is coadministered with other highly protein-bound drugs with narrow therapeutic indices, monitor the patient for AEs. 	<ul style="list-style-type: none"> • NTZ should be taken with food. • The oral suspension is not bioequivalent to the tablet formulation. • A list of clinical trials is available here: Nitazoxanide

^a Infuse over 30–120 minutes.

^b 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.⁶

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



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