Veklury®
remdesivir 100 MG FOR INJECTION

DOSING AND ADMINISTRATION FOR ADULT AND PEDIATRIC PATIENTS

INDICATION

VEKLURY is indicated for the treatment of COVID-19 in adults and pediatric patients (≥28 days old and weighing ≥3 kg), who are:

- Hospitalized, or
- Not hospitalized, have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death.

IMPORTANT SAFETY INFORMATION

Contraindication

- VEKLURY is contraindicated in patients with a history of clinically significant hypersensitivity reactions to VEKLURY or any of its components.

Please see full Prescribing Information for VEKLURY.

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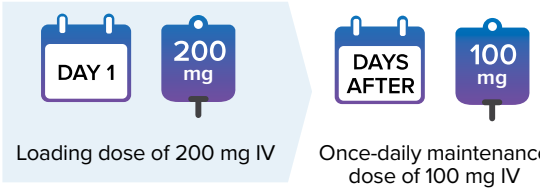
Recommended dosing[1]

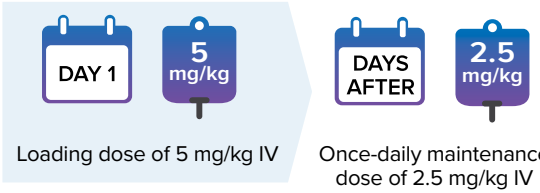
For adult and pediatric patients weighing ≥40 kg



Loading dose of 200 mg IV

Once-daily maintenance dose of 100 mg IV

For pediatric patients ≥28 days old and weighing ≥3 kg to <40 kg



Loading dose of 5 mg/kg IV

Once-daily maintenance dose of 2.5 mg/kg IV

Patients with COVID-19 and renal impairment

VEKLURY has a demonstrated safety profile in patients with renal impairment and COVID-19[1]

- Patients may receive VEKLURY regardless of renal impairment severity (eg, any eGFR), including those on dialysis.
  - NO dosage adjustment of VEKLURY is recommended in patients with any degree of renal impairment
- NO renal laboratory testing is required before or during treatment.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions

- **Hypersensitivity, including infusion-related and anaphylactic reactions:** Hypersensitivity, including infusion-related and anaphylactic reactions, has been observed during and following administration of VEKLURY; most reactions occurred within 1 hour. Monitor patients during infusion and observe for at least 1 hour after infusion is complete for signs and symptoms of hypersensitivity as clinically appropriate. Symptoms may include hypotension, hypertension, tachycardia, bradycardia, hypoxia, fever, dyspnea, wheezing, angioedema, rash, nausea, diaphoresis, and shivering. Slower infusion rates (maximum infusion time of up to 120 minutes) can potentially prevent these reactions. If a severe infusion-related hypersensitivity reaction occurs, immediately discontinue VEKLURY and initiate appropriate treatment (see Contraindications).
- **Increased risk of transaminase elevations:** Transaminase elevations have been observed in healthy volunteers and in patients with COVID-19 who received VEKLURY; these elevations have also been reported as a clinical feature of COVID-19. Perform hepatic laboratory testing in all patients (see Dosage and administration). Consider discontinuing VEKLURY if ALT levels increase to >10x ULN. Discontinue VEKLURY if ALT elevation is accompanied by signs or symptoms of liver inflammation.
- **Risk of reduced antiviral activity when coadministered with chloroquine or hydroxychloroquine:** Coadministration of VEKLURY with chloroquine phosphate or hydroxychloroquine sulfate is not recommended based on data from cell culture experiments, demonstrating potential antagonism, which may lead to a decrease in the antiviral activity of VEKLURY.

Please see full Prescribing Information for VEKLURY.

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Recommended treatment duration[1]

Recommended total duration for adult and pediatric patients who are ≥28 days old, weigh ≥3 kg, and are NOT HOSPITALIZED

3 days — For patients who are not hospitalized, have mild-to-moderate COVID-19, and are at high risk for disease progression*

Recommended total duration for adult and pediatric patients who are ≥28 days old, weigh ≥3 kg, and are HOSPITALIZED

5 days — For patients who are hospitalized and do not require invasive mechanical ventilation and/or ECMO

If a patient does not demonstrate clinical improvement, treatment may be extended up to 5 additional days, for a total treatment duration of up to 10 days

10 days — For patients who are hospitalized and require invasive mechanical ventilation and/or ECMO

*Disease progression includes hospitalization or death. Risk factors for progression include age ≥60 years, obesity (BMI ≥30 kg/m^2), chronic lung disease, hypertension, cardiovascular or cerebrovascular disease, diabetes mellitus, immunocompromised state, chronic mild or moderate kidney disease, chronic liver disease, current cancer, and sickle cell disease.

ECMO=extracorporeal membrane oxygenation.

IMPORTANT SAFETY INFORMATION (cont'd)

Adverse reactions

- The most common adverse reaction (≥5% all grades) was nausea.
- The most common lab abnormalities (≥5% all grades) were increases in ALT and AST.

Dosage and administration

— Administration should take place under conditions where management of severe hypersensitivity reactions, such as anaphylaxis, is possible.

- **Treatment duration:**
  - — For patients who **are hospitalized**, VEKLURY should be initiated as soon as possible after diagnosis of symptomatic COVID-19.
  - — For patients who are hospitalized and do not require invasive mechanical ventilation and/or ECMO, the recommended treatment duration is 5 days. If a patient does not demonstrate clinical improvement, treatment may be extended up to 5 additional days, for a total treatment duration of up to 10 days.
  - — For patients who are hospitalized and require invasive mechanical ventilation and/or ECMO, the recommended total treatment duration is 10 days.

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Preparation for infusion[1]

Product appearance

- VEKLURY for injection, 100 mg, is a sterile, preservative-free, white to off-white to yellow lyophilized powder—color does not affect product stability—in a single-dose, clear glass vial
- Red cap on vial

Dose preparation

- VEKLURY for injection, 100 mg, lyophilized powder, must be reconstituted with 19 mL Sterile Water for Injection and diluted with 0.9% sodium chloride injection prior to administration
- For pediatric patients ≥28 days old and weighing 3 kg to less than 40 kg, the 100 mg/20 mL (5 mg/mL) reconstituted solution should be further diluted to a fixed concentration of 1.25 mg/mL using 0.9% sodium chloride injection
- VEKLURY does not contain any preservatives. Once opened, do not reuse or save reconstituted or diluted VEKLURY infusion solution
- For detailed dose preparation instructions, please see full **Prescribing Information**

Reconstitution

- To reconstitute VEKLURY for injection, lyophilized powder, add 19 mL of Sterile Water for Injection using a suitably sized syringe and needle per vial
- Following reconstitution, the vial will contain 100 mg/20 mL (5 mg/mL) of remdesivir solution

Dilution

- Dilute reconstituted product immediately
- For adult and pediatric patients weighing ≥40 kg, the reconstituted solution must be diluted in either a 100 mL or 250 mL 0.9% sodium chloride injection infusion bag
- For pediatric patients ≥28 days old and weighing ≥3 kg to <40 kg, the reconstituted solution should be further diluted to a fixed concentration of 1.25 mg/mL using 0.9% sodium chloride injection

- It is always recommended to administer IV medication immediately after preparation when possible
- The prepared infusion solution is stable for 24 hours at room temperature (20 °C to 25 °C [68 °F to 77 °F]) or 48 hours at refrigerated temperature (2 °C to 8 °C [36 °F to 46 °F])

IMPORTANT: This product does not contain any preservatives. Care should be taken to prevent inadvertent microbial contamination. Any unused reconstituted or diluted VEKLURY infusion solution should be discarded.

Please see full Prescribing Information for VEKLURY.

IMPORTANT SAFETY INFORMATION (cont'd)

Dosage and administration (cont'd)

- **Treatment duration:** (cont'd)
  - For patients who are **not hospitalized**, diagnosed with mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death, the recommended total treatment duration is 3 days. VEKLURY should be initiated as soon as possible after diagnosis of symptomatic COVID-19 and within 7 days of symptom onset for outpatient use.

Administration[1]

Recommended rate of infusion*

Infusion bag volume	Infusion time	Rate of infusion
250 mL	30 minutes	8.33 mL/min
	60 minutes	4.17 mL/min
	120 minutes	2.08 mL/min
100 mL	30 minutes	3.33 mL/min
	60 minutes	1.67 mL/min
	120 minutes	0.83 mL/min

- Do not administer VEKLURY simultaneously with any other medication
- The compatibility of VEKLURY injection with IV solutions and medications other than 0.9% sodium chloride injection, USP, is not known
- Only administer VEKLURY via IV infusion over 30 to 120 minutes
- For detailed administration instructions, please see full **Prescribing Information**

*For pediatric patients ≥28 days old and weighing ≥3 kg to <40 kg, the rate of infusion (mL/min) should be calculated based on the total infusion volume and total infusion time.

IMPORTANT SAFETY INFORMATION (cont'd)

Dosage and administration (cont'd)

- **Testing prior to and during treatment:** Perform hepatic laboratory and prothrombin time testing prior to initiating VEKLURY and during use as clinically appropriate.
- **Renal impairment:** No dosage adjustment of VEKLURY is recommended in patients with any degree of renal impairment, including patients on dialysis. VEKLURY may be administered without regard to the timing of dialysis.

Pregnancy and lactation

- **Pregnancy:** A pregnancy registry has been established for VEKLURY. Available clinical trial data for VEKLURY in pregnant women have not identified a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes following second- and third-trimester exposure. There are insufficient data to evaluate the risk of VEKLURY exposure during the first trimester. Maternal and fetal risks are associated with untreated COVID-19 in pregnancy.
- **Lactation:** VEKLURY can pass into breast milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for VEKLURY and any potential adverse effects on the breastfed child from VEKLURY or from an underlying maternal condition. Breastfeeding individuals with COVID-19 should follow practices according to clinical guidelines to avoid exposing the infant to COVID-19.

Please see full Prescribing Information for VEKLURY.

The Centers for Medicare & Medicaid Services has assigned a permanent J-code, J0248, for VEKLURY® (remdesivir) when administered in an outpatient setting. This code has a 1 mg billing increment, is available for use by all payers, and is effective for dates of service on or after December 23, 2021.[2]

Effective April 1, 2022, the VEKLURY HCPCS code, J0248, has been assigned a pass-through status indicator under the hospital Outpatient Prospective Payment System.[3]

Coding requirements will vary by payer, setting of care, and date of service. Please verify patient-specific insurance benefits to confirm specific coding and billing guidelines for VEKLURY.

ADVANCING ACCESS®

An Advancing Access program specialist is available if you need further assistance, want more information, or have questions.

Call **1-800-226-2056**, M–F, 9 AM–8 PM ET

Please see full Prescribing Information for VEKLURY.

For more information, visit vekluryhcp.com.

HCPCS=Healthcare Common Procedure Coding System.

References: 1. VEKLURY. Prescribing Information. Gilead Sciences, Inc.; 2023. **2.** Special edition-COVID-19: new HCPCS code for remdesivir antiviral medication. News release. Centers for Medicare & Medicaid Services. January 7, 2022. Accessed April 18, 2023. https://www.cms.gov/outreach-and-educationoutreachffsprovpartprogprovider-partnership-email-archive/2022-01-07-mlnc-se **3.** Centers for Medicare & Medicaid Services. Pub 100-04 Medicare Claims Processing. Accessed April 18, 2023. https://www.cms.gov/files/document/r11305cp.pdf

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