Veklury® remdesivir 100 MG FOR INJECTION | LEADING THE WAY

VEKLURY eligibility for patients with COVID-19 expands

THE ONLY ANTIVIRAL APPROVED FOR PATIENTS WITH ANY STAGE OF RENAL DISEASE, INCLUDING THOSE ON DIALYSIS[1]

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.

UPDATE YOUR HOSPITAL ORDER SETS AND PROTOCOLS SO PATIENTS WITH RENAL IMPAIRMENT CAN CONSISTENTLY ACCESS VEKLURY

INDICATION

VEKLURY is indicated for the treatment of COVID-19 in adults and pediatric patients (birth to <18 years of age weighing ≥1.5 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 additional Important Safety Information throughout and full Prescribing Information here or attached.

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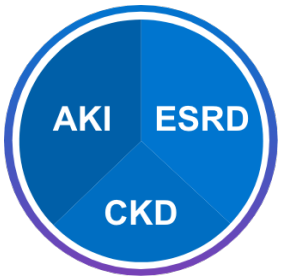
VEKLURY USE IN PATIENTS WITH RENAL IMPAIRMENT IS SUPPORTED BY CLINICAL DATA FROM THE REDPINE STUDY[1]

The REDPINE study population included:



37% of patients with acute kidney injury (n=90), defined as a 50% increase in serum creatinine within a 48-hour period that was sustained for ≥6 hours despite supportive care

26% of patients with chronic kidney disease (n=64); eGFR <30 mL/min

37% of patients with end-stage renal disease (n=89) who required hemodialysis; eGFR <15 mL/min

No new adverse reactions to VEKLURY were identified

Adverse events (all grades) were reported in 13 (8%) patients in the VEKLURY group and 3 (4%) patients in the placebo group.

- The most common adverse reactions were nausea (1%), abdominal pain (1%), and diarrhea (1%)
- No patients experienced severe adverse reactions

Study design: REDPINE (GS-US-540-5912) was a randomized, double-blind, placebo-controlled, phase 3 clinical trial in hospitalized adult patients with confirmed SARS-CoV-2 infection and a range of renal impairment severity, who received VEKLURY (n=163) or placebo (n=80) plus standard of care. Patients randomized to the VEKLURY arm received a single loading dose of VEKLURY 200 mg IV on Day 1 followed by once-daily maintenance doses of VEKLURY 100 mg IV on Days 2 through 5.

Select baseline characteristics: At baseline, patients had a range of COVID-19 severity:

- 54 patients (22%) were on room air
- 144 patients (59%) were on low-flow oxygen
- 45 patients (19%) were on high-flow oxygen
- No patients received invasive mechanical ventilation

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 additional Important Safety Information throughout and full Prescribing Information here or attached.

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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.
  - 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.
- **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.

Patients with CKD are at higher risk for progression to severe COVID-19[2]

INITIATE VEKLURY RIGHT AWAY IN PATIENTS HOSPITALIZED WITH COVID-19

LEARN MORE AT VEKLURYHCP.COM

Please see full Prescribing Information here or attached.

AKI=acute kidney injury; CKD=chronic kidney disease; ESRD=end-stage renal disease.

References: 1. VEKLURY. Prescribing Information. Gilead Sciences, Inc.; 2024. **2.** Centers for Disease Control and Prevention. Underlying medical conditions associated with higher risk for severe COVID-19: information for healthcare professionals. Updated April 12, 2024. Accessed April 24, 2024. https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html

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