

VEMLIDY: The only oral antiviral for chronic HBV infection in adults without required renal dosage adjustment¹⁻⁴

VEMLIDY is indicated for the treatment of chronic hepatitis B virus (HBV) infection in adults with compensated liver disease.

Dosing for VEMLIDY¹



Pill is to scale.

- One pill
- Once daily, with food
- No dosage adjustment for patients with eCrCl ≥ 15 mL/min or ESRD receiving chronic hemodialysis

- In patients on chronic hemodialysis, on hemodialysis days, administer VEMLIDY after completion of hemodialysis treatment
- VEMLIDY is **not recommended** in patients with ESRD (eCrCl < 15 mL/min) who are not receiving chronic hemodialysis

	eCrCl ≥ 50 mL/min	eCrCl 30-49 mL/min	eCrCl 10-29 mL/min*	ESRD on chronic hemodialysis
VEMLIDY 25 mg	No dosage adjustment required			
Tenofovir disoproxil fumarate 300 mg ^{a,b}	None	Every 48 hours	Every 72 to 96 hours	Every 7 days or after a total of approximately 12 hours of dialysis
Entecavir 0.5 mg ^{a,b}	None	0.25 mg once daily or 0.5 mg every 48 hours	0.15 mg once daily or 0.5 mg every 72 hours	0.05 mg once daily or 0.5 mg every 7 days
Entecavir 1 mg (lamivudine-refractory or decompensated liver disease) ^{a,b}	None	0.5 mg once daily or 1 mg every 48 hours	0.3 mg once daily or 1 mg every 72 hours	0.1 mg once daily or 1 mg every 7 days

IMPORTANT SAFETY INFORMATION

BOXED WARNING: POSTTREATMENT SEVERE ACUTE EXACERBATION OF HEPATITIS B

- **Discontinuation of anti-hepatitis B therapy, including VEMLIDY, may result in severe acute exacerbations of hepatitis B. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients who discontinue anti-hepatitis B therapy, including VEMLIDY. If appropriate, resumption of anti-hepatitis B therapy may be warranted.**

*VEMLIDY is **not recommended** in patients with ESRD (eCrCl < 15 mL/min) who are not receiving chronic hemodialysis.

^aGeneric tenofovir disoproxil fumarate and generic entecavir are therapeutically equivalent to the respective brand name drug. These generic drug products are designated Therapeutic Equivalence Code AB, which the FDA considers therapeutically equivalent to other pharmaceutically equivalent products. Please refer to the appropriate manufacturers of generic tenofovir disoproxil fumarate and generic entecavir for the full Prescribing Information.

^bAvailable in tablet or powder formulation for tenofovir disoproxil fumarate, or tablet or solution formulation for entecavir. Dosage shown is for adult patients with renal impairment.

This chart does not include the complete prescribing and dosing considerations for using these medications. Please refer to the full Prescribing Information for each medication. Comparison of agents does not imply comparable clinical effectiveness, safety, or tolerability. Individual prescribing decisions should be made at the discretion of the provider.

[Click here](#) for VEMLIDY full Prescribing Information, including **BOXED WARNING**.

Vemlidy[®]
tenofovir alafenamide 25mg tablets

IMPORTANT SAFETY INFORMATION (cont.)

Warnings and Precautions

• Risk of Development of HIV-1 Resistance in HBV/HIV-1 Coinfected

Patients: Due to this risk, VEMLIDY alone should not be used for the treatment of HIV-1 infection. Safety and efficacy of VEMLIDY have not been established in HBV/HIV-1 coinfecting patients. HIV antibody testing should be offered to all HBV-infected patients before initiating therapy with VEMLIDY, and, if positive, an appropriate antiretroviral combination regimen that is recommended for HBV/HIV-1 coinfecting patients should be used.

• **New Onset or Worsening Renal Impairment:** Cases of acute renal failure and Fanconi syndrome have been reported with the use of tenofovir prodrugs. In clinical trials of VEMLIDY, there have been no cases of Fanconi syndrome or proximal renal tubulopathy (PRT). Patients with impaired renal function and/or taking nephrotoxic agents (including NSAIDs) are at increased risk of renal-related adverse reactions. Discontinue VEMLIDY in patients who develop clinically significant decreases in renal function or evidence of Fanconi syndrome. Monitor renal function in all patients – See Dosage and Administration.

• **Lactic Acidosis and Severe Hepatomegaly with Steatosis:** Fatal cases have been reported with the use of nucleoside analogs, including tenofovir DF. Discontinue VEMLIDY if clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity develop, including hepatomegaly and steatosis in the absence of marked transaminase elevations.

Adverse Reactions

Most common adverse reactions (incidence ≥5%; all grades) were headache, abdominal pain, cough, back pain, fatigue, nausea, arthralgia, diarrhea, and dyspepsia.

[Click here](#) for VEMLIDY full Prescribing Information, including **BOXED WARNING** on **posttreatment severe acute exacerbation of hepatitis B**.

AASLD=American Association for the Study of Liver Diseases; eCrCl=estimated creatinine clearance; ESRD=end stage renal disease; HBV=hepatitis B virus; HIV=human immunodeficiency virus; NA=nucleos(t)ide analogue; TAF=tenofovir alafenamide; TDF=tenofovir disoproxil fumarate.

Drug Interactions

- Coadministration of VEMLIDY with drugs that reduce renal function or compete for active tubular secretion may increase concentrations of tenofovir and the risk of adverse reactions.
- Coadministration of VEMLIDY is not recommended with the following: oxcarbazepine, phenobarbital, phenytoin, rifabutin, rifampin, rifapentine, or St. John's wort. Such coadministration is expected to decrease the concentration of tenofovir alafenamide, reducing the therapeutic effect of VEMLIDY. Drugs that strongly affect P-glycoprotein (P-gp) and breast cancer resistance protein (BCRP) activity may lead to changes in VEMLIDY absorption.

Consult the full prescribing information for VEMLIDY for more information on potentially significant drug interactions, including clinical comments.

Dosage and Administration

- **Testing Prior to Initiation:** HIV infection.
- **Prior to or when initiating, and during treatment:** On a clinically appropriate schedule, assess serum creatinine, estimated creatinine clearance, urine glucose, and urine protein in all patients. In patients with chronic kidney disease, also assess serum phosphorus.
- **Dosage in Adults:** 1 tablet taken once daily with food.
- **Renal Impairment:** Not recommended in patients with end stage renal disease (ESRD; eCrCl <15 mL/min) who are not receiving chronic hemodialysis; in patients on chronic hemodialysis, on hemodialysis days, administer VEMLIDY after completion of hemodialysis treatment.
- **Hepatic Impairment:** Not recommended in patients with decompensated (Child-Pugh B or C) hepatic impairment.

References: 1. VEMLIDY Prescribing Information, Foster City, CA: Gilead Sciences, Inc.; February 2020. 2. Tenofovir disoproxil fumarate Prescribing Information, April 2019. 3. Entecavir Prescribing Information, December 2018. 4. Terrault NA, Lok ASF, McMahon BJ, et al. Update on prevention, diagnosis, and treatment of chronic hepatitis B: AASLD 2018 hepatitis B guidance. *Hepatology*. 2018;67:1560-1599.