VEMLIDY: The only oral antiviral for chronic HBV infection in adults without required renal dosage adjustment[1-3]

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

Dosing for VEMLIDY[1]

Size: 8 mm. Pill image not 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[2,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[3,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)[3,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.

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.

[a]Generic 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.

[b]Available 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.

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

Vemlidy®
tenofovir alafenamide 25mg tablets

"All NAs except TAF require dose adjustment in persons with creatinine clearance <50 mL/min."

— AASLD 2018 Hepatitis B Guidance[4]

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 coinfected 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 coinfected patients should be used.
- **New Onset or Worsening Renal Impairment:** Postmarketing cases of renal impairment, including acute renal failure, proximal renal tubulopathy (PRT), and Fanconi syndrome have been reported with TAF-containing products. 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 disoproxil fumarate (TDF). 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) in clinical studies through week 144 were headache, upper respiratory tract infection, abdominal pain, cough, back pain, arthralgia, fatigue, nausea, diarrhea, dyspepsia, and pyrexia.

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.

Pregnancy and Lactation

- **Pregnancy:** A pregnancy registry has been established for VEMLIDY. Available clinical trial data show no significant difference in the overall risk of birth defects for VEMLIDY compared with the background rate of major birth defects in the U.S. reference population.
- **Lactation:** TAF and tenofovir can pass into breast milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for VEMLIDY and any potential adverse effects on the breastfed infant from VEMLIDY or from the underlying maternal condition.

Click here for full Prescribing Information for VEMLIDY, 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; NA=nucleos(t)ide analogue; TAF=tenofovir alafenamide; TDF=tenofovir disoproxil fumarate.

References: 1. VEMLIDY Prescribing Information, Foster City, CA: Gilead Sciences, Inc.; March 2024. **2.** Viread Prescribing Information. Foster City, CA: Gilead Sciences, Inc.; April 2019. **3.** Baraclude (entecavir) Prescribing Information, Princeton, NJ: Bristol-Myers Squibb; November 2019. **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(4):1560-1599.

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Vemlidy® tenofovir alafenamide 25mg tablets