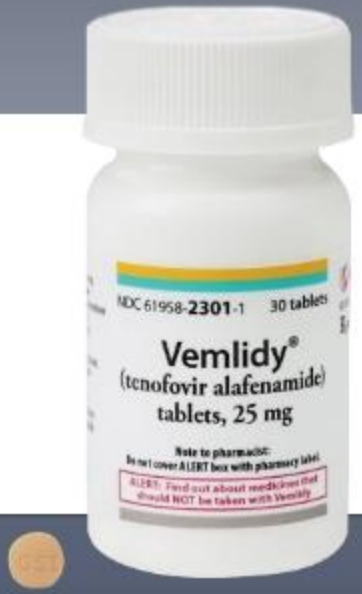
Vemlidy

(tenofovir alafenamide)



New Product
Slideshow

MPR

Introduction

- **Brand name:** Vemlidy
- **Generic name:** Tenofovir alafenamide
- **Pharmacological class:** Nucleoside analogue (reverse transcriptase inhibitor)
- **Strength and Formulation:** 25mg; tablets
- **Manufacturer:** Gilead Sciences
- **How supplied:** Bottle—30
- **Legal Classification:** Rx

VEMLIDY


NDC 61958-2301-1 30 tablets
Vemlidy®
(tenofovir alafenamide)
tablets, 25 mg
Note to pharmacist:
Do not cover ALERT box with pharmacy label.
ALERT: Find out about medicines that should NOT be taken with Vemlidy
GSI

Indications

- **Chronic hepatitis B virus (HBV) infection** in adults with compensated liver disease

Dosage & Administration

- Take with food
- **≥18 years:** 1 tab once daily
- Concomitant carbamazepine: 2 tabs once daily

Considerations for Special Populations

- **Pregnancy:** No human data to inform drug-associated risks
- **Nursing mothers:** Consider benefits and adverse effects
- **Pediatric:** <18 years: not established
- **Hepatic impairment:** Decompensated impairment (Child-Pugh B or C): not recommended
- **Renal impairment:** ESRD (CrCl<15mL/min): not recommended

Warnings/Precautions

- **Suspend therapy** if lactic acidosis or hepatotoxicity (eg, hepatomegaly, steatosis) occurs
- Women, obesity, prolonged nucleoside exposure, other known risk factors for hepatic disease: **increased risk of toxicity**
- **Monitor** closely for several months after stopping anti-hepatitis B treatment (discontinuing therapy may exacerbate HBV infection)

Warnings/Precautions

- **HBV and HIV-1 coinfection:** risk of developing HIV-1 resistance; not recommended as monotherapy for treatment of HIV-1 infection

- Perform **HIV antibody testing** prior to initiating therapy in all HBV-infected patients

Warnings/Precautions

- **Monitor** CrCl, urine glucose, urine protein, serum creatinine, serum phosphorus before and during treatment

- **Discontinue** if significant renal dysfunction or Fanconi syndrome develops

Interactions

- Concomitant drugs that strongly affect **P-gp** and **BCRP** activity may lead to changes in TAF absorption
- **Caution** with concomitant nephrotoxic agents
- **Antagonized by** carbamazepine (see Adults)

Interactions

- Concomitant with specific anticonvulsants (eg, oxcarbazepine, phenobarbital, phenytoin), antimycobacterials (eg, rifabutin, rifampin, rifapentine), St. John's wort: **not recommended**
- **May be potentiated** by drugs that decrease renal function or compete for active tubular secretion (eg, acyclovir, cidofovir, ganciclovir, valacyclovir, valganciclovir, aminoglycosides, high-dose or multiple NSAIDs)

Adverse Reactions

- Headache
- Abdominal pain
- Fatigue
- Cough
- Nausea
- Back pain

Mechanism of Action

- Tenofovir alafenamide (TAF), a prodrug of tenofovir, is converted through hydrolysis in primary hepatocytes
- Intracellular tenofovir is then converted to active tenofovir diphosphate, which inhibits HBV replication through incorporation into viral DNA by the HBV reverse transcriptase, resulting in DNA chain termination

Clinical Trials

- The efficacy and safety of Vemlidy are based on 48-week data from two randomized, double-blind, active-controlled trials: **Study 108** (N=425) and **Study 110** (N=873)

- In both studies, subjects were randomized 2:1 to receive either Vemlidy 25mg once daily or tenofovir disoproxil fumarate (TDF) 300mg once daily for 48 weeks

Clinical Trials

- **Study 108** included subjects who were HBeAg-negative treatment-naive and treatment-experienced with compensated liver disease

- **Study 110** included subjects who were HBeAg-positive treatment-naive and treatment-experienced with compensated liver disease

Clinical Trials

- The **efficacy endpoint** in both trials was the proportion of subjects with plasma HBV DNA levels <29 IU/mL at Week 48

- Other efficacy endpoints included the proportion of subjects with ALT normalization, HBsAg loss and seroconversion, and HBeAg loss and seroconversion in Study 110

Clinical Trials

- In **Study 108**, 94% of subjects in the Vemlidy group achieved HBV DNA <29 IU/mL vs. 93% in the TDF group
- The **treatment difference** was 1.8% (95% CI: −3.6% to 7.2%)

Clinical Trials

- In **Study 110**, 64% of subjects in the Vemlidy group achieved HBV DNA <29 IU/mL vs. 67% in the TDF group
- The **treatment difference** was −3.6% (95% CI:−9.8% to 2.6%)
- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  http://www.empr.com/vemlidy/drug/34623/