



Vemlidy® (tenofovir alafenamide)

Use in Acute Hepatitis B

This document is in response to your request for information regarding Vemlidy® (tenofovir alafenamide [TAF]) and its use in patients with acute hepatitis B.

Some data may be outside of the US FDA-approved prescribing information. In providing this data, Gilead Sciences, Inc. is not making any representation as to its clinical relevance or to the use of any Gilead product(s). For information about the approved conditions of use of any Gilead drug product, please consult the FDA-approved prescribing information.

The full indication, important safety information, and boxed warnings are available at: www.gilead.com/-/media/files/pdfs/medicines/liver-disease/vemlidy/vemlidy_pi.

Product Labeling¹

Indications and Usage

TAF is indicated for the treatment of chronic HBV infection in adults and pediatric patients 12 years of age and older with compensated liver disease. TAF is not indicated for use in patients with acute hepatitis B.

Clinical Guidelines on Use in Acute Hepatitis B

For recommendations regarding the treatment of patients with acute hepatitis B, please refer to the clinical guidelines (eg, www.aasld.org/practice-guidelines, <https://easl.eu/publications/clinical-practice-guidelines/>).

The inclusion of these guidelines should not be interpreted as a treatment recommendation or an endorsement of the guidelines by Gilead Sciences, Inc.

Available Data on Use in Acute Hepatitis B

A literature search was conducted in Ovid MEDLINE, BIOSIS Previews, and Embase databases for studies published between 1946 and December 21, 2023, using the search terms Vemlidy, tenofovir alafenamide, acute hepatitis B, and related search terms. No relevant citations were found.

Reference

1. Enclosed. Gilead Sciences Inc, VEMLIDY® (tenofovir alafenamide) tablets, for oral use. U.S. Prescribing Information. Foster City, CA.

Product Label

For the full indication, important safety information, and boxed warning(s), please refer to the Vemlidy US Prescribing Information available at:

www.gilead.com/-/media/files/pdfs/medicines/liver-disease/vemlidy/vemlidy_pi.

Follow Up

For any additional questions, please contact Gilead Medical Information at:

☎ 1-866-MEDI-GSI (1-866-633-4474) or 🌐 www.askgileadmedical.com

Adverse Event Reporting

Please report all adverse events to:

Gilead Global Patient Safety ☎ 1-800-445-3235, option 3 or

🌐 www.gilead.com/utility/contact/report-an-adverse-event

FDA MedWatch Program by ☎ 1-800-FDA-1088 or ✉ MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or 🌐 www.accessdata.fda.gov/scripts/medwatch

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