



# Vemlidy<sup>®</sup> (tenofovir alafenamide) Combination Therapy with Entecavir

This document presents available information regarding Vemlidy<sup>®</sup> (tenofovir alafenamide [TAF]) combination therapy with ETV in patients with chronic 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](http://www.gilead.com/-/media/files/pdfs/medicines/liver-disease/vemlidy/vemlidy_pi)**

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## Product Labeling

### 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.<sup>1</sup> TAF is not indicated for use in combination with other agents for the treatment of chronic HBV.

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## Available Data

### Case Report

There are limitations in the interpretation of case reports. Case reports cannot be generalized. Unlike controlled clinical trials, causality cannot be inferred based on uncontrolled observational data. Additionally, incidence or prevalence cannot be estimated due to the lack of a representative population sample. Other limitations of case reports include the retrospective design and publication bias.<sup>2</sup>

### **TAF + ETV in Acute Liver Injury Secondary to HBV Reactivation<sup>3</sup>**

An 82-year-old male receiving weekly rituximab for follicular lymphoma presented with the following labs: WBC of 6, Hemoglobin of 13.1, Platelets 129, total bilirubin of 0.6, alkaline phosphatase of 84, ALT 686, AST 354, and INR of 1.2. HBV serology test results were HBsAg+, HBsAb-, HBcAb IgM-, HBcAb IgG+, and HBeAg+. The patient was diagnosed with HBV reactivation, rituximab was discontinued, and TAF was initiated with baseline HBV DNA of 10,924,632 IU/mL. After 3 weeks, LFTs had worsened (ALT 3,114, AST 1,538, bilirubin 24, and INR 2.1), although HBV DNA had decreased to 1,912,539 IU/mL. Tenofovir resistance testing showed no resistance. ETV was added to TAF due to worsening LFTs, and after 6 weeks of dual therapy lab testing revealed HBV DNA 1,240 IU/mL, bilirubin 6.1, AST 39, ALT 34, and INR 1.4. The patient continues to be monitored.

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## References

1. Enclosed. Gilead Sciences Inc, VEMLIDY® (tenofovir alafenamide) tablets, for oral use. U.S. Prescribing Information. Foster City, CA.
2. Nissen T, Wynn R. The Clinical Case Report: A Review of Its Merits and Limitations. *BMC research notes*. 2014;7:264. <https://www.ncbi.nlm.nih.gov/pubmed/24758689>
3. Gonzalez A, Alomari M, Tandon K, Pacha FH, Zervos X, Kapila N. The use of combination nucleos(t)ide analogues to treat acute liver injury secondary to hepatitis B reactivation. *American Journal of Gastroenterology*. 2021;116(SUPPL):S1187. Conference: Annual Scientific Meeting of the American College of Gastroenterology (ACG). Las Vegas, NV; October 2021.

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## 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](http://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](http://www.askgileadmedical.com)

## Adverse Event Reporting

Please report all adverse events to:

Gilead Pharmacovigilance and Epidemiology ☎ 1-800-445-3235, option 3 or

🌐 <https://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](http://www.accessdata.fda.gov/scripts/medwatch)

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