



Hepsera[®] (adefovir dipivoxil) Product Retirement

This document is in response to your request for information regarding Hepsera[®] (adefovir dipivoxil) and Gilead's decision to retire the product.

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/hepsera/hepsera_pi.

Why is Gilead Retiring Hepsera?

Due to Hepsera no longer being a preferred first-line treatment option for HBV in international guidelines and the availability of alternative, guideline-recommended treatments, Gilead Sciences, Inc. has made the decision to withdraw Hepsera from sale in the US, effective as of December 31, 2022.

Notifications to withdraw the Hepsera license will be submitted to regulatory agencies in due course. The decision to withdraw this product is not the result of any new safety issues for Hepsera. Gilead believes that the withdrawal of Hepsera will not create any unmet need for patients with HBV, due to the availability of adefovir dipivoxil from other manufacturers, as well as several other authorized and guideline-recommended therapeutics with indications that would make them suitable alternatives for patients currently prescribed Hepsera.

Following the withdrawal of Hepsera, physicians can continue to prescribe generic adefovir dipivoxil or alternative regimens as they deem clinically appropriate for people living with HBV and depending upon what is approved and available in the US. Gilead will support the withdrawal of Hepsera by working with the authorities in the US and by informing patient advocacy groups and healthcare providers of the effective withdrawal date to ensure appropriate therapeutic follow-up for people living with HBV who are currently treated with Hepsera.

Gilead remains committed to the study of HBV and pursuing multiple pathways towards identifying a cure to help improve the lives of people living with the disease.

Product Label

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

www.gilead.com/-/media/files/pdfs/medicines/liver-disease/hepsera/hepsera_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

Data Privacy

The Medical Information service at Gilead Sciences may collect, store, and use your personal information to provide a response to your medical request. We may share your information with other Gilead Sciences colleagues to ensure that your request is addressed appropriately. If you report an adverse event or concern about the quality of a Gilead or Kite product, we will need to use the information you have given us in order to meet our regulatory requirements in relation to the safety of our medicines.

It may be necessary for us to share your information with Gilead's affiliates, business partners, service providers, and regulatory authorities located in countries besides your own. Gilead Sciences has implemented measures to protect the personal information you provide. Please see the Gilead Privacy Statement (www.gilead.com/privacy-statements) for more information about how Gilead handles your personal information and your rights. If you have any further questions about the use of your personal information, please contact privacy@gilead.com.

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