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GILEAD | Medical Information

Atripla® (EFV/FTC/TDF) Product Retirement

This document contains relevant information about Gilead's decision to retire the product Atripla® (efavirenz/emtricitabine/tenofovir disoproxil fumarate [EFV/FTC/TDF]).

The full indication, important safety information, and boxed warnings are available at: www.gilead.com/-/media/files/pdfs/medicines/hiv/atripla/atripla_pi.

Why is Gilead retiring Atripla®?

Due to low utilisation of Atripla®, which is no longer the preferred first line regimen in international treatment guidelines for most people living with HIV, Gilead Sciences, Inc. (Gilead) has made the decision to withdraw Atripla® from sale in your country as of December 2021.[1-3]

The decision to withdraw this product is not the result of any ongoing or new safety issues with EFV/FTC/TDF or any of its constituent parts. Gilead believes that the withdrawal of Atripla® will not create any unmet need for HIV-1 treatment, due to the availability of generic EFV/FTC/TDF, and several other authorised and guideline recommended antiretroviral agents with indications that would make them suitable alternatives for patients currently prescribed Atripla®.

Following the withdrawal of Atripla®, physicians can continue to prescribe generic EFV/FTC/TDF if available, or alternative antiretroviral regimens as they deem clinically appropriate, depending upon what is approved and available in your country for the treatment of people living with HIV. Gilead will support the withdrawal of Atripla® by working with the authorities in your country and by informing patient advocacy groups and healthcare providers in advance of the effective withdrawal date to ensure appropriate therapeutic follow-up for people living with HIV that are currently treated with Atripla®. Gilead remains committed to focusing on scientific innovation to provide new treatment options that best meet the evolving needs of people living with and affected by HIV.

References

1. U. S. Department of Health & Human Services (DHHS). Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. January 20, 2022. 2022.
2. World Health Organization (WHO). Consolidated Guidelines on HIV Prevention, Testing, Treatment, Service Delivery and Monitoring: Recommendations for a Public Health Approach. 2021:1-594.
3. European Aids Clinical Society (EACS). EACS Guidelines, Version 11.0. 2021

Product Label

For the full indication, important safety information, and boxed warning(s), please refer to the Atripla US Prescribing Information available at: www.gilead.com/-/media/files/pdfs/medicines/hiv/atripla/atripla_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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