SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. INITIALS	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	4-6. REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year			Day	Month	Year	
PRIVACY	GT					M				☐ PATIENT DIED

7+13 DESCRIBE REACTION(S) (including relevant tests/lab data) Event Verbatim [Low Level Term]
Weight gain [Weight gain] (10047896 v28.0) - Not serious - Unknown -

Insomnia [Insomnia] (10022437 v28.0) - Not serious - Unknown -

☐ LIFE THREATENING
☐ HOSPITALIZATION
☐ DISABILITY OR INCAPACITY
☐ CONGENITAL ANOMALY/BIRTH DEFECT
☐ OTHER MEDICALLY IMPORTANT CONDITION
☐ REQUIRED INTERVENTION (MEDICAL DEVICE)

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)

#1 [Suspect] Biktarvy, Coated tablet (BICTEGRAVIR;EMTRICITABINE;TENOFOVIR ALAFENAMIDE)

20. DID REACTION ABATE AFTER STOPPING DRUG?
☐ YES ☐ NO ☐ NA

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1	#1 Oral

17. INDICATION(S) FOR USE

#1 Drug use for unknown indication [Drug use for unknown indication] (10057097 v28.0)

21. DID REACTION REAPPEAR AFTER REINTRODUCTION ?
☐ YES ☐ NO ☐ NA

18. THERAPY DATES (from/to)	19. THERAPY DURATION
#1	#1

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUGS(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergics, pregnancy with last month of period, etc.)

From / To Dates	Description
# 1	

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
LABORATORIOS STEIN
Escazú, Meridiano Building, 5th floor
10203 San José CR

26. REMARKS

24b. MFR CONTROL NO.
2025000270

25b. NAME AND ADDRESS OF REPORTER
PRIVACY

24c. DATE RECEIVED BY MANUFACTURER
29-May-2025

24d. REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☐ HEALTH PROFESSIONAL ■ OTHER

DATE OF THIS REPORT
13-Jun-2025

25a. REPORT TYPE
■ INITIAL ☐ FOLLOW UP :

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Case description : Case Description: This case, manufacturer control number 2025-0715249 is a spontaneous report referring to a(n) (Gender: Male) patient. The Consumer or other Non HCP reported the following event(s) for this case:
Weight gain, Insomnia.
Medical history was not provided.
Concomitant medications were not reported by the Consumer or other Non HCP.
On an unspecified date, the patient received BIKTARVY UNK, Unknown route of administration for treatment of unknown indication.
On an unspecified date, the patient experienced Weight gain
On an unspecified date, the patient experienced Insomnia
No laboratory/diagnostic tests were reported.
The action taken with BIKTARVY was Unknown
The Consumer or other Non HCP assessed the event of Weight gain as Non-Serious, causality of Not Reported for BIKTARVY. The outcome of this event was Unknown
The Consumer or other Non HCP assessed the event of Insomnia as Non-Serious, causality of Not Reported for BIKTARVY. The outcome of this event was Unknown
The initial report was received on 29-MAY-2025 and received by Gilead Safety on 29-MAY-2025.
Duplicate numbers : 2025-0715249 (GILEAD).

14-19. Drugs

#	Name	Dosage Information	Lot/Batch	Route of Admin.	Indication	Therapy dates	Therapy duration
1	[Suspect] Biktarvy Coated tablet (BICTEGRAVIR;EMTRICITABINE;TENOFOVIR ALAFENAMIDE)			Oral	Drug use for unknown indication [Drug use for unknown indication] (10057097 v28.0)		