SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET		
		Day	Month	Year				Day	Month	Year
UNKNOWN	COSTA RICA		Unk		30 Years	Female	Unk		JUL	2025

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)

Appearance of acne on her face [Acne]

Case Description: This non-serious spontaneous report originated from Costa Rica was received by Viatris on 24-Jul-2025 (reference number: VIA-2025-CR-0009).

This initial case, received from other health professional in Costa Rica, involved a 30-Years-old female patient who reportedly experienced acne while receiving Tafil (alprazolam).

(Continued on Additional Information Page)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
- ☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING
- ☐ CONGENITAL ANOMALY
- ☐ OTHER

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) Tafil (ALPRAZOLAM) Tablet, 0.5 milligram
(Continued on Additional Information Page)

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

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

17. INDICATION(S) FOR USE
#1) Drug use for unknown indication (Produ
(Continued on Additional Information Page)

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) JUL-2025 / Unknown	#1) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

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

23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)
From/To Dates — Type of History / Notes — Description
Unknown

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
MYLANLABS
Balwant Heer
Building 4, Trident Place, Mosquito Way
Hatfield, Hertfordshire AL10 9UL UNITED KINGDOM
Phone: 44 01707853232

26. REMARKS
World Wide #: CR-MYLANLABS-2025M1063816

24b. MFR CONTROL NO.
2025M1063816

25b. NAME AND ADDRESS OF REPORTER
COSTA RICA

24c. DATE RECEIVED BY MANUFACTURER
24-JUL-2025

24d. REPORT SOURCE
☐ STUDY ☐ LITERATURE
☒ HEALTH PROFESSIONAL ☒ OTHER: Spontaneous

DATE OF THIS REPORT
03-AUG-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Medical history, current conditions and concomitant medications were not reported.

Unknown date Jul-2025 (approximately 2 weeks ago): The patient initiated alprazolam 0.5 milligram tablet at an unknown dose, unit and frequency via unknown route (batch/lot number unknown, expiration date unknown) for an unknown indication. Reporter stated, patient associates with the appearance of acne on her face, a condition she had never suffered from.

Action taken with alprazolam was unknown.

The outcome of event acne was unknown.

Case Comment: Reporter causality reported with Tafil for event acne was certain.

Company Comment: Non-Serious: Acne is an unlisted event as per company RSI of alprazolam. Causality has been assessed as possible for event acne as the contributory role of suspect drug cannot be completely excluded with available information.

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#1) Tafil (ALPRAZOLAM) Tablet, 0.5 milligram; Regimen #1	UNK; UNK	Drug use for unknown indication (Product used for unknown indication)	JUL-2025 / Unknown; Unknown