SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET Day	Month	Year
PRIVACY	COSTA RICA		PRIVACY		75 Years	Male	Unk		MAY	2025

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

Skin blisters [Blister]
mouth injury [Mouth injury]

Case Description: This non-serious solicited report (CRISL2025140334) was reported to Amgen on 15/JUL/2025 from a commercial program (PSP10856) who received this information from ASOFARMA A TU LADO with reference number CR-ADIUM-CR-0234-20250714 by a consumer and involves a 75 year old male patient who had mouth injury [PT: mouth injury], skin blisters [PT: blister] while receiving Vectibix.

(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) Vectibix (panitumumab) Solution for injection, 20 milligram per millilitre

(Continued on Additional Information Page)

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

15. DAILY DOSE(S)
#1) 20 milligra (Continued on Additional Information Page)

16. ROUTE(S) OF ADMINISTRATION
#1) Intravenous use

17. INDICATION(S) FOR USE
#1) Colon cancer (Colon cancer)

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

18. THERAPY DATES(from/to)
#1) 08-APR-2025 / Unknown

19. THERAPY DURATION
#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 to Ongoing	Current Condition	Colon cancer (Colon cancer)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
Amgen Biotecnológica S.A.S.
Ana Carolina Uribe
Cra 7 No. 123-35 Torre 123 Piso 6
Bogotá, COLOMBIA
Phone: 57 3157008539

26. REMARKS

24b. MFR CONTROL NO.
CRISL2025140334

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.

NAME AND ADDRESS WITHHELD.

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

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

DATE OF THIS REPORT
20-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

No historical medical condition was reported. The patient's current medical condition included colon cancer. No concomitant medications were provided. No co-suspect medications were reported.

The patient began Vectibix on 08/APR/2025. On an unknown date in MAY/2025, the patient had a mouth injury, skin blisters. The patient during an in-person visit reported that he had not taken any medication for these reported symptoms. He reported that he was exposed to the sun daily without sunscreen for more than 4 hours a day because he goes to his farm to work.

No treatment information was received. The outcome of the events mouth injury, blister were reported as not recovered/not resolved. Action taken with Vectibix was reported as unknown for the events mouth injury and blister.

The other manufacturer reported that the events mouth injury, blister were possibly related to Vectibix. The causal relationship between the events mouth injury, blister and Vectibix were possibly related by the consumer.

Follow up is not possible.

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) Vectibix (panitumumab) Solution for injection, 20 milligram per millilitre; Regimen #1	20 milligram, q2wk, 100 MG en 5 ML x 1 INY x 1 ECO; Intravenous use	Colon cancer (Colon cancer)	08-APR-2025 / Unknown; Unknown