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
PRIVACY	COSTA RICA		PRIVACY		51 Years	Male	Unk	10	MAR	2025

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

mouth ulcer [Mouth ulcer]
Skin involvement, mainly on palms and soles [Skin disorder]

Case Description: This serious spontaneous report (CRISP2025054536) was reported to Amgen on 17/MAR/2025 from ASOFARMA A TU LADO with reference number CR-ADIUM-CR-0101-20250317 by a consumer and involves a 51 year old female patient who had mouth ulcer [PT: mouth ulceration], skin involvement, mainly on palms and soles [PT: skin disorder] 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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 408 milligram, q2wk/every 2 weeks	#1) Intravenous use

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 14-SEP-2024 / Unknown	#1) Unknown

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

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

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 Ltd.
Ana Carolina Uribe
Cra 7 No. 123-35 Torre 123 Piso 6
Bogotá, COLOMBIA
Phone: 57 3157008539

26. REMARKS
World Wide #: CR-AMGEN-CRISP2025054536

24b. MFR CONTROL NO.
CRISP2025054536

24c. DATE RECEIVED BY MANUFACTURER
09-APR-2025

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

DATE OF THIS REPORT
15-APR-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

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

NAME AND ADDRESS WITHHELD.

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 reported. No co-suspect medications were reported.

The patient began Vectibix on 14/SEP/2024. On 10/MAR/2025, the patient had mouth ulcer and skin involvement, mainly on palms and soles in MAR/2025. The patient reported general skin involvement, but more so on the soles of his feet and palms of her hands. In addition to this involvement, she reported small blisters in her mouth that make it impossible for her to eat or drink. For this reason, her treating physician discontinued the product for one month, giving her time to recover. On 10/MAR/2025, she was given a 10% Urea cream kit, at her treating physician's request. On 12/APR/2025, the patient would restart the treatment following a medical evaluation.

The outcome of the events mouth ulceration, skin disorder were reported as not recovered/not resolved. Action taken with Vectibix was temporarily withheld for the events mouth ulceration and skin disorder.

The causal relationship between the events mouth ulceration, skin disorder and Vectibix was not provided by the consumer. The other manufacturer reported that the events mouth ulceration, skin disorder were possibly related to Vectibix.

Follow up is not possible.

ADDITIONAL INFORMATION RECEIVED ON 09/APR/2025: In this follow-up report; the case was downgraded to non serious. The patient demographic (gender) was updated. This case refers to a male patient. The patient restarted the therapy on 12/APR/2025 following medical evaluation. It was confirmed that the patient continues with the events, improved with urea cream at 10% , but continued. The outcome of the events, mouth ulceration, skin disorder were reported as recovering/resolving.