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		43 Years	Male	Unk	10	AUG	2025

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

The rash was spread over the entire body, including face, back, arms [Rash]

Case Description: This non-serious solicited report (CRISP2025168542) was reported to Amgen on 20/AUG/2025 by a consumer from a commercial program (PSP10856) Asofarma Centroamerica y Caribe with reference number CR-ADIUM-CR-0274-20250820and involves a 43 year old male patient who had rash which was spread over the entire body, including face, back, arms [PT: rash] while receiving Vectibix.

No historical medical condition was reported.

(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)
#1) 315 milligram, q2wk

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

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

18. THERAPY DATES(from/to)
#1) 06-AUG-2025 / Ongoing

19. THERAPY DURATION
#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 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.
CRISP2025168542

24c. DATE RECEIVED BY MANUFACTURER
20-AUG-2025

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

DATE OF THIS REPORT
28-AUG-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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

NAME AND ADDRESS WITHHELD.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

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 06/AUG/2025. On 10/AUG/2025, during the visit, the patient had rash which was spread over the entire body, including face, back, arms, abdomen, legs, and torso.

The outcome of the event rash was reported as not recovered/not resolved. Action taken with Vectibix was continued for the event rash.

The consumer and the other manufacture reported that the event rash was possibly related to Vectibix.

The reporter declined consent for follow up. No follow up attempts are possible. No further information is expected.