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		64 Years	Female	Unk		APR	2025

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

Severe fatigue [Fatigue]
skin rash/rash is all over [Generalized rash]

Case Description: This non-serious solicited report (CRISL2025167044) was reported to Amgen on 19/AUG/2025 from a commercial program (PSP10856) who received this information from ASOFARMA A TU LADO with reference number CR-ADIUM-CR-0271-20250819 by a consumer and involves a 64 year old female patient who experienced severe fatigue [PT: fatigue], skin rash/rash was all over [PT: rash] 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

15. DAILY DOSE(S)
#1) 400 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) 11-APR-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		

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.
CRISL2025167044

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

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

DATE OF THIS REPORT
25-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

No historical medical condition was reported. No current medical condition was reported. No concomitant medications were provided. No co-suspect medications were reported.

The patient began Vectibix on 11/APR/2025. On an unknown date in APR/2025 since starting treatment, the patient had severe fatigue. On an unknown date in JUL/2025, the patient had skin rash all over.

No treatment information was received. The outcome of the events fatigue, rash were reported as not recovered/not resolved. Action taken with Vectibix was continued for the events fatigue and rash.

The consumer reported that the events fatigue, rash were possibly related to Vectibix.

Follow up is not possible.