CIOMS FORM

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			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year				Day	Month	Year	
PRIVACY	COSTA RICA		PRIVACY		Unk	Male	Unk		JUL	2025	

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

Indication: Melanoma Off label use [Off label use]
Generalized dermatological reaction [Generalized skin reaction]

Case Description: This non-serious solicited report (CRISL2025154541) was reported to Amgen on 01/AUG/2025 via Asofarma Centroamerica y Caribe reference number CR-ADIUM-CR-0248-20250801 by a other health professional from a commercial program (PSP10856) and involves a male patient who had generalized dermatological reaction [PT: skin reaction] while receiving Vectibix. Off label use 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
(Continued on Additional Information Page)

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

15. DAILY DOSE(S)
#1) UNK (100 (Continued on Additional Information Page)

16. ROUTE(S) OF ADMINISTRATION
#1) Unknown

17. INDICATION(S) FOR USE
#1) Melanoma (Malignant melanoma)
(Continued on Additional Information Page)

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

18. THERAPY DATES(from/to)
#1) JUL-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	Melanoma (Malignant melanoma)

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.
CRISL2025154541

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

NAME AND ADDRESS WITHHELD.

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

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

DATE OF THIS REPORT
07-AUG-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 melanoma. No concomitant medications were provided. No co-suspect medications were reported.

The patient began Vectibix on an unknown date in JUL/2025. The patient being treated with Vectibix 20 mg/mL concentrated solution for infusion at an unknown dose for the indication melanoma which was considered as off label use. On an unknown date in JUL/2025, the patient had generalized dermatological reaction.

No treatment information was received. The outcome of the event skin reaction was reported as not recovered/not resolved. Action taken with Vectibix was reported as unknown for the event skin reaction.

The other health professional and the other health professional institution reported that the event skin reaction was possibly related to Vectibix.

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

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	UNK (100 MG en 5 ML x 1 INY x 1 FCO); Unknown	Melanoma (Malignant melanoma) Off label use in unapproved indication (Off label use)	JUL-2025 / Unknown; Unknown