

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY DOMINICAN REPUBLIC	2. DATE OF BIRTH Day Month Year PRIVACY			2a. AGE 56 Years	3. SEX Female	3a. WEIGHT Unk	4-6 REACTION ONSET Day Month Year Unk			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION <input type="checkbox"/> PATIENT DIED <input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION <input type="checkbox"/> INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY <input type="checkbox"/> LIFE THREATENING
7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data) Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas) grade II acneiform skin rash on the upper trunk (both anterior and posterior) [Rash acneiform] Case Description: This is a spontaneous report received from a Physician. A 56-year-old female patient received encorafenib (ENCORAFENIB), for colon cancer metastatic, braf gene mutation; cetuximab (CETUXIMAB) for colon cancer metastatic, braf gene mutation. The patient's relevant medical history and concomitant medications were not reported. (Continued on Additional Information Page)											

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1) Encorafenib (ENCORAFENIB) Capsule #2) CETUXIMAB (CETUXIMAB) (Continued on Additional Information Page)		20. DID REACTION ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
15. DAILY DOSE(S) #1) #2)	16. ROUTE(S) OF ADMINISTRATION #1) Unknown #2) Unknown	
17. INDICATION(S) FOR USE #1) BRAF-mutated metastatic colon cancer #2) BRAF-mutated metastatic colon cancer (Continued on Additional Information Page)		21. DID REACTION REAPPEAR AFTER REINTRODUCTION? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
18. THERAPY DATES(from/to) #1) Unknown #2) Unknown	19. THERAPY DURATION #1) Unknown #2) 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		

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER Pfizer S.A. Laura Arce Mora Avenida Escazú, Torre Lexus, piso 7. Escazú San Jose, COSTA RICA		26. REMARKS
	24b. MFR CONTROL NO. PV202500076887	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 25-JUN-2025	24d. REPORT SOURCE <input type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input checked="" type="checkbox"/> HEALTH PROFESSIONAL <input checked="" type="checkbox"/> OTHER: Spontaneous	
DATE OF THIS REPORT 30-JUN-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The following information was reported: DERMATITIS ACNEIFORM (non-serious), outcome "recovered", described as "grade II acneiform skin rash on the upper trunk (both anterior and posterior)". The action taken for encorafenib and cetuximab was unknown. Therapeutic measures were taken as a result of dermatitis acneiform.

Additional information: The event was handled in conjunction with Dermatology with doxycycline, corticosteroids and sunscreen, initiating the descent at one week and with complete resolution without further complications at 2 weeks.

No follow-up attempts are 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) Encorafenib (ENCORAFENIB) Capsule; Regimen #1	; Unknown	BRAF-mutated metastatic colon cancer (Colon cancer metastatic) BRAF-mutated (BRAF gene mutation)	Unknown; Unknown
#2) CETUXIMAB (CETUXIMAB) ; Regimen #1	; Unknown	BRAF-mutated metastatic colon cancer (Colon cancer metastatic) BRAF-mutated (BRAF gene mutation)	Unknown; Unknown