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| SUSPECT ADVERSE REACTION REPORT | |
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I. REACTION INFORMATION

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| 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 |
| 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) | | | | | | | <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 |

II. SUSPECT DRUG(S) INFORMATION

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| 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

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| 22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction) |
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| 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

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| 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 |