

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

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|--|----------------------------------|------------------|----------------|------|-------------------------------|-------------------------|--------------------------|--------------------|-------|------|--|
| 1. PATIENT INITIALS (first, last) PRIVACY | 1a. COUNTRY COSTA RICA | 2. DATE OF BIRTH | | | 2a. AGE 77 Years | 3. SEX Female | 3a. WEIGHT Unk | 4-6 REACTION ONSET | | | 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 |
| | | Day | Month | Year | | | | Day | Month | Year | |
| | | | PRIVACY | | | | | Unk | | | |

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
 Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas)
 dryness on the skin of her forearms, hands, legs, and especially her heels [Dry skin]
 itching [Itching]
 discouraged and very tired [Discouragement]
 discouraged and very tired [Tiredness]
 moderate to severe pain, including pain in her lower limbs and legs/ her legs hurt a lot [Pain in leg]
 cramps [Cramps]
 hip problem and she cannot walk much [Hip discomfort]
 hip problem and she cannot walk much/ could not walk long distances

(Continued on Additional Information Page)

II. SUSPECT DRUG(S) INFORMATION

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| 14. SUSPECT DRUG(S) (include generic name) #1) Ibrance (PALBOCICLIB) Capsule (Lot # GJ9157; Exp.Dt. JUN-2026) (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) 125 mg, cyc (Continued on Additional Information Page) | 16. ROUTE(S) OF ADMINISTRATION #1) Unknown | |
| 17. INDICATION(S) FOR USE #1) Unknown | | 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 | 19. THERAPY DURATION #1) 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) | | |
| 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. PV202500011712 | 25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD. |
| 24c. DATE RECEIVED BY MANUFACTURER 11-AUG-2025 | 24d. REPORT SOURCE <input type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input checked="" type="checkbox"/> HEALTH PROFESSIONAL <input checked="" type="checkbox"/> OTHER: Spontaneous | NAME AND ADDRESS WITHHELD. |
| DATE OF THIS REPORT 11-AUG-2025 | 25a. REPORT TYPE <input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> FOLLOWUP: 3 | NAME AND ADDRESS WITHHELD. |

11-Aug-2025 14:05

ADDITIONAL INFORMATION**7+13. DESCRIBE REACTION(S) continued**

[Difficulty in walking]

Case Description: This is a spontaneous report received from a Nurse and Consumer or other non HCPs, Program ID: 164974.

A 77-year-old female patient received palbociclib (IBRANCE), (Lot number: GJ9157, Expiration Date: Jun2026) at 125 mg cyclic (125 mg, cyclic (3 weeks and rest 1 week)). The patient's relevant medical history and concomitant medications were not reported. The following information was reported: DRY SKIN (non-serious), outcome "unknown", described as "dryness on the skin of her forearms, hands, legs, and especially her heels"; PRURITUS (non-serious), outcome "unknown", described as "itching"; DISCOURAGEMENT (non-serious), FATIGUE (non-serious), outcome "unknown" and all described as "discouraged and very tired"; PAIN IN EXTREMITY (non-serious), outcome "unknown", described as "moderate to severe pain, including pain in her lower limbs and legs/ her legs hurt a lot"; MUSCLE SPASMS (non-serious), outcome "unknown", described as "cramps"; MUSCULOSKELETAL DISCOMFORT (non-serious), outcome "not recovered", described as "hip problem and she cannot walk much"; GAIT DISTURBANCE (non-serious), outcome "not recovered", described as "hip problem and she cannot walk much/ could not walk long distances". The action taken for palbociclib was unknown.

Additional information: On 23Jul2025 it was reported that caregiver got in touch to request the Uber benefit, said that the patient was not technological and indicated that the patient could not walk long distances. Also on 24Jul2025 patient reported that her legs hurt a lot and for that reason she could not travel by bus nor climb stairs. On 01Aug2025 reporter indicated that Yesterday, 31Jul2025, patient had a procedure and her health was a little bit affected (they did not refer to the procedure performed). No further information was obtained because reporter asked to be called later and ended the call.

Follow-up (05Feb2025): This is a spontaneous follow-up report received from a consumer, Program ID: 164974

Updated information: New events added: "Hip discomfort" and "Difficulty in walking"

Follow-up (14Mar2025): Follow-up attempts are completed.

Follow-up (23Jul2025 and 24Jul2025): This is a spontaneous follow-up report received from a Consumer or other non HCPs, Program ID: 164974.

Updated information included: Clinical course and event information updated

Follow-up (01Aug2025): This is a spontaneous follow-up report received from a Consumer or other non HCP, Program ID: 164974

Updated information: Event details added in narrative

AMENDMENT: This Follow-up report is being submitted to amend previously reported information: Event "malaise" was removed.

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) Ibrance (PALBOCICLIB) Capsule {Lot # GJ9157; Exp.Dt. JUN-2026}; Regimen #1 | 125 mg, cyclic (3 weeks and rest 1 week); Unknown | Unknown | Unknown; Unknown |