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		77 Years	Female	Unk		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)

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
- ☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING

II. SUSPECT DRUG(S) INFORMATION

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? ☐ YES ☐ NO ☐ 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? ☐ YES ☐ NO ☐ NA

18. THERAPY DATES(from/to)
#1) 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		

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.
PV202500011712

24c. DATE RECEIVED BY MANUFACTURER
23-JUL-2025

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

DATE OF THIS REPORT
28-JUL-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 2

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

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.

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

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