SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET Day	Month	Year
PRIVACY	COSTA RICA		PRIVACY		66 Years	Female	Unk		MAR	2024

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

Other Serious Criteria: Medically Significant
retinal wear in both eyes and I have already lost one [Blindness, one eye]
retinal wear in both eyes [Retinal disorder]
Tiredness [Tiredness]
Diarrhea [Diarrhea]
a leg half touched, it started with like a pain 4 months ago [Pain in leg]

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

(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

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) Ibrance (PALBOCICLIB) Unknown {Lot # GF2469; Exp.Dt. MAR-2026}
(Continued on Additional Information Page)

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

15. DAILY DOSE(S)
#1) 125 mg, 1x/day

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

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.
PV202300192472

24c. DATE RECEIVED BY MANUFACTURER
25-APR-2025

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

DATE OF THIS REPORT
30-APR-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 6

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

A 66-year-old female patient received palbociclib (IBRANCE), first regimen (Lot number: GF2469, Expiration Date: Mar2026) at 125 mg 1x/day, oral, second regimen since 2023 (Lot number: Gt9342, Expiration Date: Nov2025) at 125 mg cyclic (daily for 21 days and rest 7 days) and third regimen (ongoing) (Lot number: G19157, Expiration Date: 06Dec2026) at 125 mg cyclic (daily for 21 days and rest 7 days). The patient's relevant medical history and concomitant medications were not reported. The following information was reported: PAIN IN EXTREMITY (non-serious) with onset Mar2024, outcome "unknown", described as "a leg half touched, it started with like a pain 4 months ago"; BLINDNESS UNILATERAL (medically significant), outcome "unknown", described as "retinal wear in both eyes and I have already lost one"; RETINAL DISORDER (medically significant), outcome "unknown", described as "retinal wear in both eyes"; FATIGUE (non-serious), outcome "recovering", described as "Tiredness"; DIARRHOEA (non-serious), outcome "recovering", described as "Diarrhea". Minor events handled correctly at home. The reporter considered events were non-serious. Start of treatment: about one year. On 03Jan2025, Patient indicated she has retinal wear in both eyes and have already lost one, the other is the one that works for her, so she almost cannot distinguish anything. On 25Apr2025, patient commented, "It is that before my son was the one who accompanied me and he is the one who helped me with the PRIVACY because I have problems with my eyesight, but now he cannot go tomorrow, 26Apr with me, but one of my daughters goes. I have wear and tear on my retina, I am under control here at the hospital in PRIVACY, but I have an appointment now in September, I even have to have an exam before that appointment, it seems to me that the appointment is in August and the appointment in September." In addition, she mentioned: "I had already reported this when I go to appointments, because I do not distinguish sight much, it does not help me to distinguish, that is why they accompany me." Take into account that the patient indicated that she has the vision problem long before consuming the medication. The action taken for palbociclib was dosage not changed. Therapeutic measures were taken as a result of fatigue, diarrhoea.

Follow-up (25Dec2023): This is a spontaneous follow-up report received from the same contactable Nurse, Program ID: 164974.
Updated information included: Added Patient Route of Administration, expiration date and treatment was updated to Yes.

Follow-up (17Jan2024): This is a spontaneous follow-up report received from a Nurse.
Updated information: suspect drug data, event outcome and reporter assessment.

Follow-up (08Jul2024): This is a spontaneous follow-up report received from a consumer (patient), Program ID: 164974.
Updated information: New reporter. Product details (new dosage regimen in 2023). New event (''a leg half touched, it started with like a pain 4 months ago''). Additional information of start of treatment.

Follow-up (14Aug2024): This is a spontaneous follow-up report received via a completed questionnaire:
Updated information: Second dosage lot number and expiry date added.

Follow-up (05Nov2024): Follow-up attempts are completed.

Amendment: This follow-up report is being submitted to amend previous information: Follow-up #6 date in the narrative was updated from 25Sep2024 to 05Nov2024.

Follow-up (03Jan2025): This is a spontaneous follow-up report received from the same contactable consumer (patient).
Updated information included: New events: Blindness, one eye, Retinal disorder. Case is upgraded to serious.
Follow-up (27Mar2025): Follow-up attempts are completed.

Follow-up (25Apr2025): This is a spontaneous follow-up report received from the same contactable consumer (patient). Updated information included: suspect drug details (dosage regimen) and clinical course details.

Case Comment: Based upon the available infromation, the serious events blindness unilateral and retinal disorder are mostly considered age related events not associated to the Administration of palbociclib.

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) Unknown {Lot # Gt9342; Exp.Dt. NOV-2025}; Regimen #2	daily for 21 days and rest 7 days; Unknown	Unknown	2023 / Unknown; Unknown
#1) Ibrance (PALBOCICLIB) Unknown {Lot # G19157; Exp.Dt. 06-DEC-2026}; Regimen #3	daily for 21 days and rest 7 days; Unknown	Unknown	Ongoing; Unknown