

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY DOMINICAN REPUBLIC	2. DATE OF BIRTH			2a. AGE 71 Years	3. SEX Female	3a. WEIGHT Unk	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		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)
passed away [Unknown cause of death]
three times a day, with a dose of 200 mg [Drug use for unapproved dosing regimen]

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

A 71-year-old female patient received palbociclib (IBRANCE), at 200 mg 3x/day. The patient's relevant medical history and concomitant medications were not reported.

(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		20. DID REACTION ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
15. DAILY DOSE(S) #1) 200 mg, 3x/day	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 checked="" type="checkbox"/> 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. PV202500063743	
24c. DATE RECEIVED BY MANUFACTURER 26-MAY-2025	24d. REPORT SOURCE <input type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL <input checked="" type="checkbox"/> OTHER: Spontaneous	
DATE OF THIS REPORT 28-MAY-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	
		25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD. NAME AND ADDRESS WITHHELD. NAME AND ADDRESS WITHHELD.

28-May-2025 01:33

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

The following information was reported: DEATH (death), outcome "fatal", described as "passed away"; PRODUCT USE ISSUE (non-serious), outcome "unknown", described as "three times a day, with a dose of 200 mg". Per clinical course, the patient was called to check if she was still taking the medication Ibrance. The person who answered was the patient's daughter, who said that the patient had passed away. It was confirmed that the patient was undergoing treatment with Ibrance. She reported that the patient took the medication three times a day, with a dose of 200 mg. When asked for information about the batch and expiration date of the product, the patient's granddaughter responded that there was another person waiting for the treatment, and they decided to donate the medication after her grandmother passed away. The date and cause of death for the patient were unknown. It was not reported if an autopsy was performed.