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		
		Day	Month	Year				Day	Month	Year
PRIVACY	HONDURAS		PRIVACY		86 Years	Female	Unk	26	JUL	2025

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

The patient experienced death [Death NOS]

Case Description: This solicited case was received in HONDURAS and concerned a patient participating in the patient support program with protocol number (IC4-05520-001-HND) (Improve adherence to treatments).

(Continued on Additional Information Page)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☒ PATIENT DIED Date: 26-JUL-2025
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
- ☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING
- ☐ CONGENITAL ANOMALY
- ☐ OTHER

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) INDAPAMIDE 1.5MG/AMLODIPINE 5MG-F-32 (INDAPAMIDE 1.5 mg, AMLODIPINE 5 mg) Modified-release
(Continued on Additional Information Page)

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) UNK	#1) Oral use

17. INDICATION(S) FOR USE
#1) (Product used for unknown indication)

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☒ NA

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) Unknown	#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
SERVIER CENTRO AMERICA Y CARIBE
PANAMA

26. REMARKS
Patient ID: 0511193800016
Study ID: IC4-05520-001-HND*

24b. MFR CONTROL NO.
S25011451

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

24c. DATE RECEIVED BY MANUFACTURER
05-AUG-2025

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

DATE OF THIS REPORT
06-AUG-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: S25011451

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The initial reporter was a Consumer's relative.

The patient (ID:0511193800016) was an 86-year-old female with unknown medical history.
The patient has been treated with INDAPAMIDE 1.5MG/AMLODIPINE 5MG-F-32 (unknown daily dose, orally) since unknown date for an unknown indication.
No concomitant treatment was reported if any.

On 26-JUL-2025, the patient experienced a death. The patient's relative suspected that the same medications (she didn't specify which ones) could have been the cause of death; however, she said she reserved the right of not to provide information. The patient's relative didn't know if the patient was taking INDAPAMIDE 1.5MG/AMLODIPINE 5MG-F-32 at the time of her death, because they had someone else in charge of that.

Action taken regarding INDAPAMIDE 1.5MG/AMLODIPINE 5MG-F-32: Not applicable.
Outcome: Fatal.

Reporter assessment : Serious event. Causality was not assessed.

Consent to contact the doctor was not obtained. Case closed.

Case Comment: Death is considered an outcome. In this case, no further information about the clinical circumstances leading to death is provided. The limited available information precludes an accurate case assessment.

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) INDAPAMIDE 1.5MG/AMLODIPINE 5MG-F-32 (INDAPAMIDE 1.5 mg, AMLODIPINE 5 mg) Modified-release tablet; Regimen #1	UNK; Oral use	(Product used for unknown indication)	Unknown; Unknown