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	COSTA RICA		PRIVACY		70 Years	Female	Unk		MAY	2025

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

Low blood pressure [Blood pressure low]

Case Description: This solicited case was received from a Pharmacist regarding a patient participating in study with protocol IC4-06593-001-CRI (Improve adherence to treatments) in COSTA RICA.

The patient was a 70 year-old (patient ID 104890989) female with unspecified medical history treated with PERINDOPRIL ARG 10 / INDA 2.5 / AMLO 5-F35 (unknown daily dose) since unknown date for unknown indication.

(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
- ☐ CONGENITAL ANOMALY
- ☐ OTHER

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) PERINDOPRIL ARG 10 / INDA 2.5 / AMLO 5-F35 (PERINDOPRIL ARGININE 10 mg, INDAPAMIDE 2.5 mg,
(Continued on Additional Information Page)

15. DAILY DOSE(S)
#1) UNK, Unknown

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

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

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

19. THERAPY DURATION
#1) Unknown

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

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

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 PANAMA
COSTA RICA

26. REMARKS
Patient ID: 104890989
Study ID: IC4-06593-001-CRI*

24b. MFR CONTROL NO.
S25011639

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

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

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

DATE OF THIS REPORT
13-AUG-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: S25011639

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

No concomitant treatments were reported, if any.

On an unknown date in MAY-2025, she experienced Low blood pressure due to PERINDOPRIL ARG 10 / INDA 2.5 / AMLO 5-F35. The pharmacist did not know if she had already recovered.

Action taken regarding PERINDOPRIL ARG 10 / INDA 2.5 / AMLO 5-F35: Unknown, no confirmation was obtained as to whether she continued PERINDOPRIL ARG 10 / INDA 2.5 / AMLO 5-F35 or not.

Outcome of the Low blood pressure: Unknown.
Reporter assessment : Related. Not serious.

Consent to contact the doctor was not obtained.
FU requested to the reporter

Case Comment: Hypotension is listed as per RSI of PERINDOPRIL ARG 10 / INDA 2.5 / AMLO 5-F35. Considering the known side effect with missing information (medical history, indication, therapy and event dates, outcome, investigations, action taken) the causal role is conditional.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Blood pressure measurement Low		

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) PERINDOPRIL ARG 10 / INDA 2.5 / AMLO 5-F35 (PERINDOPRIL ARGININE 10 mg, INDAPAMIDE 2.5 mg, AMLODIPINE 5 mg) Tablet, 10/2.5/5 mg; Regimen #1	UNK, Unknown; Unknown	(Product used for unknown indication)	Unknown; Unknown