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	PANAMA		PRIVACY		46 Years	Female	Unk		DEC	2024

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

Patient experienced high blood pressure because she went on a trip to Guatemala and the altitude affected her [Blood pressure high]
Patient took 2 tablets of PERINDOPRIL ARG 5 / INDA 1.25 / AMLO 5-F36 [Intentional product use issue]

Case Description: This case was received from a Consumer concerning a patient participating in patient support program related to protocol number (IC4-06593-001-PAN) in PANAMA.

The patient was a 46-year-old female with a medical history of

(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 5 / INDA 1.25 / AMLO 5-F36 (PERINDOPRIL ARGININE 5 mg, INDAPAMIDE 1.25 mg,

(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) 1 DF, qd	#1) Oral use

17. INDICATION(S) FOR USE
#1) Hypertension (Hypertension)

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) JAN-2024 / DEC-2024	#1) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) Glisulin (Metformin hydrochloride) ; 2022 / Ongoing

23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

From/To Dates	Type of History / Notes	Description
JAN-2024 to Ongoing	Historical Condition	Hypertension (Hypertension)
2022 to Ongoing	Historical Condition	Prediabetes (Glucose tolerance impaired)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
SERVIER CENTRO AMERICA Y CARIBE
PANAMA

26. REMARKS
Patient ID: 188934855
Study ID: IC4-06593-001-PAN*

24b. MFR CONTROL NO.
S25010825

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

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

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

DATE OF THIS REPORT
04-AUG-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: S25010825

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Hypertension since unknown date in JAN-2024, treated with PERINDOPRIL ARG 5 / INDA 1.25 / AMLO 5-F36 (1DF daily, orally) from an unknown date in JAN-2024 to DEC-2024, than (2 DF daily, orally) from an unknown date in DEC-2024 to JAN-2025, and (1 DF daily, orally) from an unknown date in JAN-2025 , Prediabetes since an unknown date in 2022, treated with Metformin hydrochloride (100 mg daily) from an unknown date in 2022 to ongoing.

No other concomitant treatment was reported if any.

On an unknown date in DEC-2024, patient experienced high blood pressure because she went on a trip to Guatemala and the altitude affected her, so her doctor told her to take 2 tablets daily of PERINDOPRIL ARG 5 / INDA 1.25 / AMLO 5-F36 and her blood pressure stabilized. On an unknown date in JAN-2025 she returned to 1 tablet daily.

Treatment of the reaction (High blood pressure): On an unknown date in DEC-2024, she took 2 tablets daily of PERINDOPRIL ARG 5 / INDA 1.25 / AMLO 5-F36 instead of 1 by medical prescription.

Action taken regarding PERINDOPRIL ARG 5 / INDA 1.25 / AMLO 5-F36 was dose increased

Outcome: Recovered

The seriousness assessment as per reporter was non-serious.

The causality assessment as per reporter was Not related.

No consent obtained to contact reporter or physician. Case closed.

Case Comment: Hypertension is unlisted in the RSI of PERINDOPRIL ARG 5 / INDA 1.25 / AMLO 5-F36. Given the history of hypertension and the context of possible transient trigger (high altitude), along with recovery following dose increase, the reporter's opinion is maintained and the causal role is assessed as not related.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	DEC-2024	Blood pressure measurement High		

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 5 / INDA 1.25 / AMLO 5-F36 (PERINDOPRIL ARGININE 5 mg, INDAPAMIDE 1.25 mg, AMLODIPINE 5 mg) Tablet, 5/1.25/5 mg; Regimen #1	1 DF, qd; Oral use	Hypertension (Hypertension)	JAN-2024 / DEC-2024; Unknown
#1) PERINDOPRIL ARG 5 / INDA 1.25 / AMLO 5-F36 (PERINDOPRIL ARGININE 5 mg, INDAPAMIDE 1.25 mg, AMLODIPINE 5 mg) Tablet, 5/1.25/5 mg; Regimen #2	2 DF, qd (increased form 1 tablet to 2)); Oral use	Hypertension (Hypertension)	DEC-2024 / JAN-2025; Unknown
#1) PERINDOPRIL ARG 5 / INDA 1.25 / AMLO 5-F36 (PERINDOPRIL ARGININE 5 mg, INDAPAMIDE 1.25 mg, AMLODIPINE 5 mg) Tablet, 5/1.25/5 mg; Regimen #3	1 DF, qd; Oral use	Hypertension (Hypertension)	JAN-2025 / Ongoing; Unknown