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		67 Years	Male	61.00 kg		APR	2025

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

Low potassium [Potassium low]

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

The patient was a 67-year-old male (Height: 177 cm and Weight: 61 kg) with a medical history of Hypertension since unknown date in 2005, treated with PERINDOPRIL ARG 5 / INDA 1.25 / AMLO 5-F36 (1DF daily, orally) since unknown date in 2023 to unknown date in APR-2025, Cholesterol problems since birth, treated with Rosuvastatin (20 mg daily,

(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)

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 1 DF, qd	#1) Oral use

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 2023 / APR-2025	#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)
#1) Rosuvastatin (Rosuvastatin) ; 2015 / Unknown

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

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Historical Condition since birth	Blood cholesterol abnormal (Blood cholesterol abnormal)
2005 to Ongoing	Historical Condition	Hypertension (Hypertension)

IV. MANUFACTURER INFORMATION

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

26. REMARKS
Patient ID: 64949
Study ID: IC4-06593-001-PAN*

24b. MFR CONTROL NO.
S25010249

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

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

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

DATE OF THIS REPORT
25-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: S25010249

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

orally) since unknown date in 2015.

No other concomitant treatment was reported if any.

On an unknown date in APR-2025, the patient experienced Low potassium.

Patient doctor told that one of the components of TRIPLIXAM (it was not known which one) was lowering his potassium, so he changed it to COVERAM 5/5MG.

Treatment for the reaction (Low potassium) was unknown.

On an unknown date in APR-2025, doctor changed TRIPLIXAM 5/1.25/5MG to COVERAM 5/5MG.

Action taken regarding PERINDOPRIL ARG 5 / INDA 1.25 / AMLO 5-F36 was drug withdrawn.
Outcome: Recovered.

The seriousness assessment as per reporter was non-serious.

The causality assessment as per reporter was related.

Consent to contact the doctor was not obtained.

Case Comment: Blood potassium decreased is listed as per RSI of PERINDOPRIL ARG 5 / INDA 1.25 / AMLO 5-F36. Considering the known side effect, positive dechallenge with missing information (definitive therapy and event dates, investigations) the causal role is probable.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Blood potassium 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 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)	2023 / APR-2025; Unknown