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	GUATEMALA		PRIVACY		82 Years	Female	63.00 kg			2022

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

Very low blood pressure [Blood pressure low]
Blocked kidney [Hydronephrosis]
Urinary tract infection [Urinary tract infection]
Patient took half tablet daily of PERINDOPRIL ARG 10 / INDA 2.5 / AMLO 10-F34 by own decision and economic factors, her doctor prescribed 1 tablet daily [Intentional misuse by dose change]
If her blood pressure rose, patient took PERINDOPRIL ARG 10 / INDA 2.5 / AMLO 10-F34 even though her doctor stopped her from taking it [Intentional product misuse]
Patient took half tablet daily of PERINDOPRIL ARG 10 / INDA 2.5

(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 10-F34 (PERINDOPRIL ARGININE 10 mg, INDAPAMIDE 2.5 mg,

(Continued on Additional Information Page)

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 0.5 DF, qd	#1) Oral use

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

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 2022 / FEB-2025	#1) Unknown

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
1990 to Ongoing	Historical Condition	Hypertension (Hypertension)
2021 to Ongoing	Historical Condition	Osteoporosis (Osteoporosis)

IV. MANUFACTURER INFORMATION

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

26. REMARKS
Patient ID: 1811323620103
Study ID: IC4-06593-001-GTM*

24b. MFR CONTROL NO.
S25012272

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

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

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

DATE OF THIS REPORT
26-AUG-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

/ AMLO 10-F34 by own decision and economic factors, her doctor prescribed 1 tablet daily [Drug use for unapproved dosing regimen]

Case Description: This Solicited case was received from a Consumer in GUATEMALA concerned a patient participating in patient support program (PSP) protocol number IC4-06593 -001-GTM (Improve adherence to treatments).

The patient was an 82-years old female (patient ID: 1811323620103) with the medical history of hypertension since 1990 treated with PERINDOPRIL ARG 10 / INDA 2.5 / AMLO 10-F34 (half tablet daily, orally) from an unknown date in 2022 to an unknown date in FEB-2025 and osteoporosis since 2021.

No other concomitant treatments were reported, if any.

In 2022, she experienced Misuse because she took half tablet daily of PERINDOPRIL ARG 10 / INDA 2.5 / AMLO 10-F34 by own decision and economic factors, her doctor prescribed 1 tablet daily. If her blood pressure rose, she took PERINDOPRIL ARG 10 / INDA 2.5 / AMLO 10-F34 even though her doctor stopped her from taking it.

On an unknown date in FEB-2025, she experienced very low blood pressure and blocked kidney, her doctor suspended PERINDOPRIL ARG 10 / INDA 2.5 / AMLO 10-F34. She related the event Very low blood pressure to the kidney problems she had. She did not know the intensity.

O an unknown date in JUN-2025, she experienced urinary tract infection. It was not obtained to what she related it. The intensity was not obtained.

Treatment of the reaction (urinary tract infection): Since unknown date she took an antibiotic (she did not know the name).

Action taken regarding PERINDOPRIL ARG 10 / INDA 2.5 / AMLO 10-F34: Temporarily interrupted. In FEB-2025 doctor suspended PERINDOPRIL ARG 10 / INDA 2.5 / AMLO 10-F34.

Outcome: Recovered for Patient took half tablet daily of PERINDOPRIL ARG 10 / INDA 2.5 / AMLO 10-F34 by own decision and economic factors, her doctor prescribed 1 tablet daily, patient took PERINDOPRIL ARG 10 / INDA 2.5 / AMLO 10-F34even though her doctor stopped her from taking it, very low blood pressure and not recovered for blocked kidney, urinary tract infection.

The seriousness assessment as per reporter was non-serious.

Causality assessment was related for misuse- considered as not applicable for patient took half tablet daily of PERINDOPRIL ARG 10 / INDA 2.5 / AMLO 10-F34 by own decision and economic factors, her doctor prescribed 1 tablet daily and She took PERINDOPRIL ARG 10 / INDA 2.5 / AMLO 10-F34 even though her doctor stopped her from taking it.

Causality assessment was not related for Very low blood pressure, Blocked kidney and Urinary tract infection.

Consent to contact the doctor was not obtained.

Case Comment: Hydronephrosis and Urinary tract infection are unlisted while Hypotension is listed as per RSI of TRIPLIXAM (PERINDOPRIL ARGININE 10 mg, INDAPAMIDE 2.5 mg, AMLODIPINE 10 mg). Considering the known side effect and positive dechallenge for Hypotension the causal role is possible. While considering the missing information (detailed history, unspecified kidney problem, investigations, treatment of osteoporosis) and negative dechallenge the causal role is not related for Hydronephrosis and Urinary tract infection.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	FEB-2025	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 10-F34 (PERINDOPRIL ARGININE 10	0.5 DF, qd; Oral use	Hypertension (Hypertension)	2022 / FEB-2025; Unknown

Mfr. Control Number: S25012272

ADDITIONAL INFORMATION

14-19. SUSPECT DRUG(S) continued

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mg, INDAPAMIDE 2.5 mg, AMLODIPINE 10 mg) Tablet, 10/2.5/10 mg; Regimen #1			