SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET Day	Month	Year
PRIVACY	COSTA RICA		PRIVACY		39 Years	Female	73.00 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)

Before COVERAM patient was treated with COVERSYL [Drug use in unapproved population]
At the pharmacy they told her that this medicine (Coversyl) no longer existed, so they told her to take COVERAM [Drug dispensing issue]
Patient took COVERAM without consulting her doctor [Self-medication]
Patient took half tablet daily of COVERAM 5/5MG [Underdose]
Patient took half tablet daily of COVERAM 5/5MG by own decision [Intentional drug misuse]

Case Description: This solicited case was received from a Consumer

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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 ARGININE 5-AMLODIPINE 5-F31 (PERINDOPRIL ARGININE 5 mg, AMLODIPINE 5 mg) Tablet,

(Continued on Additional Information Page)

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

15. DAILY DOSE(S)
#1) 0.5 DF, qd

16. ROUTE(S) OF ADMINISTRATION
#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)
#1) APR-2025 / Ongoing

19. THERAPY DURATION
#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
2021 to Ongoing	Historical Condition	Hypertension (Hypertension)
2021 to MAR-2025	Historical Drug	
	Daily dose: Half a tablet daily for hypertension	

(Continued on Additional Information Page)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
Servier PANAMA
COSTA RICA

26. REMARKS
Patient ID: 304060020
Study ID: IC4-05985-001-CRI*

24b. MFR CONTROL NO.
S25010513

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

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

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

DATE OF THIS REPORT
31-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

concerning a patient participating in the patient support program with protocol IC4-05985-001-CRI (Improve patient adherence to the treatments) in COSTA RICA.

The patient was a 39-year-old female (weight 73 kg, height 150 cm) with a medical history of Hypertension since 2021 treated with PERINDOPRIL ARGININE 5-AMLODIPINE 5-F31 (0.5 DF daily, orally) from unknown date in APR-2025 to present.

The patient was previously on Perindopril NOS (2.5 mg daily, orally) between 2021 to Mar-2025 for Hypertension.

Concomitant treatments included Supplements (did not specify names) (unknown daily dose), since not reported date for unknown indication.

No other concomitant treatments were reported, if any.

In Apr-2025, she experienced self-medication because the doctor prescribed COVERSYL 5mg, but at the pharmacy they told her that this medicine (COVERSYL) no longer existed, so they told her to take PERINDOPRIL ARGININE 5-AMLODIPINE 5-F31 and she took it without consulting her doctor.

In Apr-2025, she had misuse, she took half tablet daily of COVERAM 5/5MG by own decision.

Action taken regarding COVERAM 5/5MG: Maintained.

Outcome: Recovered (special situation)

Reporter causality was considered as not applicable, and event seriousness was not reported.

Consent to contact the doctor was not obtained.

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 ARGININE 5-AMLODIPINE 5-F31 (PERINDOPRIL ARGININE 5 mg, AMLODIPINE 5 mg) Tablet, 5/5 mg; Regimen #1	0.5 DF, qd; Oral use	Hypertension (Hypertension)	APR-2025 / Ongoing; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
2021 to MAR-2025	Historical Drug	Coversyl 5mg (Coversyl); Drug Indication: Hypertension (Hypertension) Daily dose: Half a tablet daily for hypertension