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		59 Years	Female	65.00 kg	08	MAY	2025

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

Cough [Cough]
Diagnostic of high cholesterol problems [High cholesterol]

Case Description: This solicited case was received from COSTA RICA and concerned a patient participating in the post-authorization study (IC4-05985-001-CRI) (Improve patient adherence to the treatments).

(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 ARGININE 3.5-AMLODIPINE 2.5-F40 (PERINDOPRIL ARGININE 3.5 mg, AMLODIPINE 2.5 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) 08-MAY-2025 / 08-JUN-2025	#1) 1 month 1 day

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) Metformina (Metformina) ; APR-2025 / Ongoing

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

From/To Dates	Type of History / Notes	Description
2018 to Ongoing	Historical Condition	Hypertension (Hypertension)
APR-2025 to Ongoing	Historical Condition	Prediabetes (Glucose tolerance impaired)

IV. MANUFACTURER INFORMATION

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

26. REMARKS
Patient ID: 106660098
Study ID: IC4-05985-001-CRI*

24b. MFR CONTROL NO.
S25009189

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

24c. DATE RECEIVED BY MANUFACTURER
25-JUN-2025

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

DATE OF THIS REPORT
08-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: S25009189

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The initial reporter was a Consumer's relative.

The patient was a 59 year-old female (Weight: 65 kg, Height 148 cm) with the medical history of Hypertension since unknown date in 2018, treated with PERINDOPRIL ARGININE 3.5-AMLODIPINE 2.5-F40 (1 DF daily, orally) from 08-MAY-2025 to 08-JUN-2025 and Prediabetes since APR-2025 treated with Metformina (unknown daily dose, orally) since APR-2025.
No concomitant treatment was reported, if any.

On 08-May-2025, the patient experienced Cough. The intensity of the event and outcome were not obtained.
On unknown date in 05-JUN-2025, the patient was diagnostic of high cholesterol problems. Causal relationship with Servier drug and the intensity of the event were not obtained.
Treatment of the reaction (Diagnostic of high cholesterol problems): On 05-JUN-2025 the patient took Rosustar, 1 tablet daily, orally.

Action taken with PERINDOPRIL ARGININE 3.5-AMLODIPINE 2.5-F40: Drug withdrawn
Outcome: Unknown for Cough
Not recovered from Diagnostic of high cholesterol problems

The case was reported as non-serious.
Reporter assessment : event cough was assessed as related and diagnostic of high cholesterol was not assessed by the reporter.

Consent to contact the doctor was obtained.

Case Comment: Cough is listed as per PERINDOPRIL ARGININE-AMLODIPINE RSI, while blood cholesterol increased is unlisted. Considering plausible chronology, the known side effect and missing information on dechallenge result, the causal role is assessed as possible for cough. Due to the short onset latency in relation to the progressive nature of the event, the causal relationship for blood cholesterol increased seems unlikely.

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 3.5-AMLODIPINE 2.5-F40 (PERINDOPRIL ARGININE 3.5 mg, AMLODIPINE 2.5 mg) Tablet; Regimen #1	1 DF, qd; Oral use	Hypertension (Hypertension)	08-MAY-2025 / 08-JUN-2025; 1 month 1 day