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		71 Years	Female	67.00 kg	12	JUN	2025

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

Dizziness. Couldn't get up from where she was. Relate it to the blood pressure variation. [Dizziness]
Uncontrolled blood pressure [Blood pressure inadequately controlled]
Height loss [Body height decreased]
Headache due to high blood pressure [Headache]

Case Description: This solicited case was received in COSTA RICA and concerned a patient participating in the post-authorization study (IC4-06593-001-CRI) (Improve patient adherence to the treatments). The initial reporter was a Consumer.

(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 5-F35 (PERINDOPRIL ARGININE 10 mg, INDAPAMIDE 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) 11-JUN-2025 09:07:00 / Ongoing	#1) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) Atenolol (Atenolol) ; 1995 / Ongoing

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

From/To Dates	Type of History / Notes	Description
1985 to Ongoing	Historical Condition	Hypertension (Hypertension)
APR-2025 to 11-JUN-2025	Historical Drug for unknown diagnosis	

(Continued on Additional Information Page)

IV. MANUFACTURER INFORMATION

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

26. REMARKS
Patient ID: 202901327
Study ID: IC4-06593-001-CRI*

24b. MFR CONTROL NO.
S25008394

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

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

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

DATE OF THIS REPORT
23-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: S25008394

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The patient was an 71-year-old female (Patient ID: 202901327) (weight: 67 kg) with a medical history of Hypertension since an unknown date in 1985 treated with PERINDOPRIL ARG 10 / INDA 2.5 / AMLO 5-F35 (1 DF daily, orally) since 11-JUN-2025 at 09:07 and Atenolol (100 mg daily, orally) since unknown date in 1995.

Past drug included Irbesartan (150 mg at unknown daily dose) and Amlodipine (50 mg at unknown daily dose), both since unknown date in APR-2025 to 11-Jun-2025 for unknown indication.

No other concomitant treatment was reported if any.

On 12-Jun-2025, the patient experienced Dizziness, she couldn't get up from where she was. The patient also reported that when her blood pressure rose or fell, she felt dizzy.
Since an unknown date, the patient experienced uncontrolled blood pressure. She went to the emergency room four times because her blood pressure rose to 100/190 mmHg. (she had high blood pressure since before taking the Servier medication). The intensity of the event and the causal relationship with the Servier medication were not determined. On 12-Jun-2025 she had blood pressure at 80/25 mmHg.
On an unknown date, the patient experienced Height loss (Height decreases with age). The severity of the event and the causal relationship with the Servier
medication were not determined.
On an unknown date, the patient experienced Headache, due to high blood pressure. The severity of the event and the causal relationship with the Servier
medication were not determined.

Actions taken with PERINDOPRIL ARG 10 / INDA 2.5 / AMLO 5-F35: Maintained.
Outcome: Recovering for Dizziness.
Unknown for Height loss and Headache.
Not recovered for uncontrolled blood pressure.
Reporter assessment : No causality assessment reported for all events. Not serious.
FU requested to the reporter.
Consent to contact the doctor was not obtained.

Case Comment: Dizziness and Headache are listed while Blood pressure inadequately controlled and Body height decreased are unlisted as per RSI of TRIPLIXAM (PERINDOPRIL ARGININE 10 mg, INDAPAMIDE 2.5 mg, AMLODIPINE 5 mg). Considering the compatible chronology, ongoing suspect medication with missing information (detailed investigations, outcome) the causal role is possible for Dizziness, Headache and Blood pressure inadequately controlled while unlikely for Body height decreased.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Blood pressure measurement 100/190 mmHg		139/89 100/60
2	12-JUN-2025	Blood pressure measurement 80/25 mmHg		139/89 100/60

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 5-F35 (PERINDOPRIL ARGININE 10 mg, INDAPAMIDE 2.5 mg, AMLODIPINE 5 mg) Tablet, 10/2.5/5 mg; Regimen #1	1 DF, qd; Oral use	Hypertension (Hypertension)	11-JUN-2025 09:07:00 / Ongoing; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
APR-2025 to 11-JUN-2025	Historical Drug	Irbesartan 150mg (Irbesartan); Drug Indication: Drug use for unknown indication (Product used for unknown indication)

ADDITIONAL INFORMATION

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
	for unknown diagnosis	
APR-2025 to 11-JUN-2025	Historical Drug	Amlodipin 5mg (Amlodipin); Drug Indication: Drug use for unknown indication (Product used for unknown indication)
	for unknown diagnosis	