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		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 patient support program (IC4-06593-001-CRI) (Improve patient adherence to the treatments). The initial reporter was 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 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
#2) Melatonin (Melatonin) ; 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
16-JUL-2025

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

DATE OF THIS REPORT
08-AUG-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The patient (Patient ID: 202901327) was a 71-year-old female (weight: 67 kg) with the medical history of Hypertension since 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, Insomnia since 2015 treated with Melatonin (unknown daily dose) and Agapantine (unknown daily dose); both since unknown date .
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 indications.

No other concomitant treatment was reported if any.

On 12-JUN-2025, the patient experienced Dizziness, she could not 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).
On 12-JUN-2025, the patient had blood pressure at 80/25 mmHg.
On an unknown date, the patient experienced Height loss (Height decreases with age).
On an unknown date, the patient experienced Headache, due to high blood pressure.
On 21-JUN-2025, the patient recovered from all adverse events, as soon as his doctor told her to stop taking the Ibersartan and Amlodipine she was taking and that she would only take PERINDOPRIL ARG 10 / INDA 2.5 / AMLO 5-F35.
The events were moderate.
The patient clarified that the headache she had on 15-JUL-2025 (reported by her relative) was not severe and was because she sometimes had trouble sleeping and because she was up late she got a bit of a headache, but it was not related to her blood pressure. Insomnia occurred occasionally, she had it since 2015, and for this she took Melatonina and Agapantina (daily dose and milligrams were not obtained).

Actions taken with PERINDOPRIL ARG 10 / INDA 2.5 / AMLO 5-F35: Dose not changed
Outcome: Recovered

Reporter assessment:
Patient attributed headache to other causes than PERINDOPRIL ARG 10 / INDA 2.5 / AMLO 5-F35.
No causality assessment reported for all events. Not serious

SIGNIFICANT FOLLOW UP INFORMATION (16-JUL-2025): Patient details updated: Height added. Medical history updated: Insomnia added. New concomitant treatment Melatonin added. Event information updated: Outcome changed to recovered and stop date added for event PT "Dizziness", "Blood pressure inadequately controlled", "Body height decreased" and "Headache". Severity was updated to moderate for event PT "Dizziness" . Severity (moderate) added for event PT "Blood pressure inadequately controlled", "Body height decreased" and "Headache". Causality as reported for event PT "Headache" updated to not related. Narrative updated.

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, context og trouble while sleeping contributing to headache with missing information (detailed investigations) 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 /	1 DF, qd; Oral use	Hypertension (Hypertension)	11-JUN-2025 09:07:00

Mfr. Control Number: S25008394

ADDITIONAL INFORMATION

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
AMLO 5-F35 (PERINDOPRIL ARGININE 10 mg, INDAPAMIDE 2.5 mg, AMLODIPINE 5 mg) Tablet, 10/2.5/5 mg; Regimen #1			/ Ongoing; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
APR-2025 to 11-JUN-2025	Historical Drug for unknown diagnosis	Irbesartan 150mg (Irbesartan); Drug Indication: Drug use for unknown indication (Product used for unknown indication)
APR-2025 to 11-JUN-2025	Historical Drug for unknown diagnosis	Amlodipin 5mg (Amlodipin); Drug Indication: Drug use for unknown indication (Product used for unknown indication)
2015 to Ongoing	Historical Condition	Insomnia (Insomnia);