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		82 Years	Female	92.00 kg		MAY	2025

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

Very high blood pressure [Blood pressure high]
The patient took 2 tablets of PRETERAX 5/1.25MG daily [Drug use for unapproved dosing regimen]

Case Description: This solicited case was received from a Consumer concerning a patient participating in the patient support program with protocol IC4-06590-001-CRI (Improve patient adherence to the treatments) in COSTA RICA.

The patient was a 82-year-old female (weight 92 kg, height 148 cm) with a

(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 5MG/INDAPAMIDE 1.25-F31 (PERINDOPRIL ARGININE 5 mg, INDAPAMIDE 1.25 mg)
(Continued on Additional Information Page)

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

15. DAILY DOSE(S)
#1) 1 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) MAY-2025 / JUL-2025

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)
#1) Venosmil (Hidrosmin) ; 2023 / Unknown
#2) Dapagliflozine (Dapagliflozin) ; MAY-2025 / Ongoing
#3) Rosuvastatine (Rosuvastatin calcium) ; 2024 / Ongoing
#4) Famotidine (Famotidine) ; Ongoing
#5) Acetylsalicylic acid (Acetylsalicylic acid) ; Ongoing
#6) Rivastigmine (Rivastigmine hydrogen tartrate) ; Ongoing

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

From/To Dates	Type of History / Notes	Description
1989 to Ongoing	Historical Condition	Hypertension (Hypertension)
2023 to Ongoing	Historical Condition	

(Continued on Additional Information Page)

IV. MANUFACTURER INFORMATION

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

26. REMARKS
Patient ID: 500990132
Study ID: IC4-06590-001-CRI*

24b. MFR CONTROL NO.
S25011294

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

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

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

DATE OF THIS REPORT
11-AUG-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: S25011294

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

medical history of Hypertension since 1989, treated with PERINDOPRIL ARG 5MG/INDAPAMIDE 1.25-F31 (1 DF daily, orally) since MAY-2025 to JUL-2025 then dose increased to (2 DF Daily, orally) and PRETERAX 10mg/2.5mg (1 DF Daily, orally) since an unknown date, Circulation problems since 2023, treated with Hidrosmin (Unknown daily dosage) since an unknown date in 2023, Acetylsalicylic acid (Unknown daily dosage) since an unknown date, Early onset Alzheimer's since an unknown date, treated with Rivastigmine hydrogen tartrate (Unknown daily dosage) and Gastric protector since an unknown date, treated with Famotidine (Unknown daily dosage) since an unknown date.

Other medical history included, Knee replacement, Overweight, colon cancer survivor,.

Other concomitant medications included, Dapagliflozin (Unknown daily dosage) since an unknown date in MAY-2025, Rosuvastatin calcium (Unknown daily dosage) since an unknown date in 2024 and for unknown indication.

The patient was previously on Codiovan (not reported dose and miligrams) between not reported dates for Hypertension.

No other concomitant treatments were reported, if any.

In May-2025, she experienced Very high blood pressure due to PERINDOPRIL ARG 5MG/INDAPAMIDE 1.25-F31. She started with 1 tablet of PERINDOPRIL ARG 5MG/INDAPAMIDE 1.25-F31 daily but after a week (exact date not indicated) her blood pressure rose significantly (160-179 mmHg), after 1 month her doctor told her to take 2 tablets of PERINDOPRIL ARG 5MG/INDAPAMIDE 1.25-F31 daily and 2 days later (exact date not indicated) her blood pressure was regulated. She told the doctor that if instead of giving the patient 2 tablets of PPERINDOPRIL ARG 5MG/INDAPAMIDE 1.25-F31, it would be better to give her only 1 tablet of PRETERAX 10/2.5mg.

Action taken regarding PERINDOPRIL ARG 5MG/INDAPAMIDE 1.25-F31: Dose increased
Outcome: Recovered
Reporter causality assessment was provided as : Related. Seriousness: not serious.

Consent to contact the doctor was not obtained.

Case Comment: Hypertension is unlisted as per RSI of PERINDOPRIL ARG 5MG/INDAPAMIDE 1.25-F31. Considering the given details, recovery with increased dosage with missing information (detailed investigations) the causal role is possible.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	MAY-2025	Blood pressure measurement 160-179 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 5MG/INDAPAMIDE 1.25-F31 (PERINDOPRIL ARGININE 5 mg, INDAPAMIDE 1.25 mg) Film-coated tablet, 5-1.25 mg; Regimen #1	1 DF, qd; Oral use	Hypertension (Hypertension)	MAY-2025 / JUL-2025; Unknown
#1) PERINDOPRIL ARG 5MG/INDAPAMIDE 1.25-F31 (PERINDOPRIL ARGININE 5 mg, INDAPAMIDE 1.25 mg) Film-coated tablet, 5-1.25 mg; Regimen #2	2 DF, qd; Oral use	Hypertension (Hypertension)	Unknown; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
2023 to Ongoing	Historical Condition	Unspecified circulatory system disorder (Cardiovascular disorder);
Unknown	Historical Condition	Knee replacement (Knee arthroplasty);

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ADDITIONAL INFORMATION

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Historical Condition	Overweight (Overweight);
Unknown	Historical Condition	Colon cancer (Colon cancer);
Unknown to Ongoing	Historical Condition	Early onset Alzheimer's disease (Dementia Alzheimer's type);
Unknown	Historical Drug	Codiovan (Codiovan); Drug Indication: Hypertension (Hypertension)
Unknown	Historical Condition	Gastric disorder (Gastrointestinal disorder);