# 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 | HONDURAS | | PRIVACY | | 63 Years | Male | 97.00 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)

Prostate surgery [Prostate surgery]
He experienced high blood pressure of 130-140 mm Hg [Blood pressure high]
Leg inflammation and Foot inflammation [Inflammation]
Prostate inflammation [Prostatitis]
High creatinine [Creatinine high]
Fluid retention [Fluid retention]

Case Description: This solicited case was received in HONDURAS and concerned a patient participating in the patient support program (IC4- 06593-001-HND) (Improve adherence to 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 ARG 10 / INDA 2.5 / AMLO 10-F34 (PERINDOPRIL ARGININE 10 mg, INDAPAMIDE 2.5 mg,
#2 ) PROCORALAN 5 mg (IVABRADINE) Film-coated tablet, 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 |
| #2 ) 2.5 mg, qd | #2 ) Oral use |

17. INDICATION(S) FOR USE
#1 ) Hypertension (Hypertension)
#2 ) Heart problems (Cardiac disorder)

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☒ NA

| 18. THERAPY DATES(from/to) | 19. THERAPY DURATION |
|---|---|
| #1 ) 2021 / APR-2025 | #1 ) Unknown |
| #2 ) 2021 / Ongoing | #2 ) 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 Ongoing | Historical Condition | Heart disease, unspecified (Cardiac disorder) |

## IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
SERVIER CENTRO AMERICA Y CARIBE
PANAMA

26. REMARKS
Patient ID: 1804196101638
Study ID: IC4-06593-001-HND*

24b. MFR CONTROL NO.
**S25011180**

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

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

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

DATE OF THIS REPORT
07-AUG-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

## ADDITIONAL INFORMATION

**7+13. DESCRIBE REACTION(S) continued**

The initial reporter was a Consumer.

The patient was a 63-year-old male (Weight: 97 kg; Height: 175 cm) with the medical history of Hypertension since 2021, treated with PERINDOPRIL ARG 10 / INDA 2.5 / AMLO 10-F34 (1 DF daily, orally) from unknown date in 2021 to unknown date in APR-2025 and Heart problems since 2021, treated with PROCORALAN 5 mg (2.5 mg daily, orally) since unknown date in 2021.
No other concomitant treatment was reported, if any.

On unknown date in APR-2025, the patient experienced High blood pressure (130-140 mm Hg). He related it to prostate inflammation, not to PERINDOPRIL ARG 10 / INDA 2.5 / AMLO 10-F34 or PROCOLARAN.

On unknown date in APR-2025, the patient experienced Leg inflammation and Foot inflammation. He related it to prostate inflammation, not to PERINDOPRIL ARG 10 / INDA 2.5 / AMLO 10-F34 or PROCOLARAN.

On unknown date in APR-2025, the patient experienced Prostate inflammation. Because of this, he had prostate surgery 2 and a half months ago (unknown date in MAY 2025).

On unknown date in APR-2025, the patient experienced High creatinine. He related it to prostate inflammation, not to PERINDOPRIL ARG 10 / INDA 2.5 / AMLO 10-F34 or PROCOLARAN. The Intensity was not obtained.

On unknown date in APR-2025, the patient experienced Fluid retention. He related it to prostate inflammation, not to PERINDOPRIL ARG 10 / INDA 2.5 / AMLO 10-F34 or PROCOLARAN. The Intensity was not obtained.

Treatment of the reactions : Since APR-2025, the patient took Exforge (he did not know the miligrams and dose)

Action taken with PERINDOPRIL ARG 10 / INDA 2.5 / AMLO 10-F34: Drug withdrawn
Action taken with PROCOLARAN 5MG: Dose not changed
Outcome: Recovered.

The event PT "Prostatic operation" was upgraded to serious (hospitalization) by the MAH.

Reporter´s assessment: Events not related to the suspected Servier products. Non-serious

Since no consent to contact the physician neither the reporter was obtained, the case was closed

Case Comment: Blood creatinine increased is listed in the RSI of both PERINDOPRIL ARG 10 / INDA 2.5 / AMLO 10-F34 and PROCOLARAN, while hypertension is listed for PROCOLARAN only. Given the context provided (event occurring due to prostate inflammation), nature of some events (surgery, signs of urinary outflow impairment), the reporter;s opinion is maintained and the causal role is assessed as not related.

**13. Lab Data**

| # | Date | Test / Assessment / Notes | Results | Normal High / Low |
|---|---|---|---|---|
| 1 | | Blood pressure measurement<br><br>130-140 mm Hg | | |

**14-19. SUSPECT DRUG(S) continued**

| 14. SUSPECT DRUG(S) (include generic name) | 15. DAILY DOSE(S);<br>16. ROUTE(S) OF ADMIN | 17. INDICATION(S) FOR USE | 18. THERAPY DATES (from/to);<br>19. THERAPY DURATION |
|---|---|---|---|
| #1 ) PERINDOPRIL ARG 10 / INDA 2.5 / AMLO 10-F34 (PERINDOPRIL ARGININE 10 mg, INDAPAMIDE 2.5 mg, AMLODIPINE 10 mg) Tablet, 10/2.5/10 mg; Regimen #1 | 1 DF, qd; Oral use | Hypertension (Hypertension) | 2021 / APR-2025; Unknown |