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		87 Years	Female	Unk		JUN	2025

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

Low sodium [Sodium low]
Worsening of cholesterol problems [Blood cholesterol abnormal]
Worsening of cholesterol problems [Condition worsened]
Diagnostic of Heart problem [Heart disorder]

Case Description: This solicited case was received from a consumer regarding a patient participating in the study with protocol IC4-06520-001-CRI (Improve patient adherence to the treatments) in COSTA RICA. The initial reporter was the patient's relative.

(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) INDAPAMIDE 1.5MG-F37 (INDAPAMIDE 1.5 mg) Coated tablet, 1.5 mg

(Continued on Additional Information Page)

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 1.5 mg, qd	#1) Oral use

17. INDICATION(S) FOR USE
#1) Hypertension (Hypertension)

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 2020 / Unknown	#1) Unknown

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

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

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) Carbimen (Lercanidipine hydrochloride) 10 mg; Ongoing
#2) Toreza (Rosuvastatin calcium) 20 mg; Ongoing

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

From/To Dates	Type of History / Notes	Description
2010 to Ongoing	Historical Condition	Hypertension (Hypertension)
2015 to Ongoing	Historical Condition	Blood cholesterol abnormal (Blood cholesterol abnormal)

IV. MANUFACTURER INFORMATION

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

26. REMARKS
Patient ID: 900070604
Study ID: IC4-06520-001-CRI*

24b. MFR CONTROL NO.
S25011240

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

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

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

DATE OF THIS REPORT
08-AUG-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: S25011240

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The patient was an 87 years old female (height 150 cm) with a medical history of Hypertension since 2010 treated with INDAPAMIDE 1.5MG-F37 (1.5 mg daily) since 2020 then (1.5 mg daily, oral) since unknown date, Lercanidipine hydrochloride (10 mg daily, oral) from an unknown date to an unknown date then (10 mg daily, oral) since unknown date, Cholesterol problems since 2015 treated with Rosuvastatin calcium (20 mg daily, oral) since unknown date to unknown date.

She had been treated with NATRILIX SR 1.5MG (1 tablet daily, orally) between 2020 to not reported date and then from not reported to not reported date for Hypertension. She took NATRILIX for the first time 5 years ago and stopped taking it, but her relative did not know why it was stopped and the dates
No other concomitant treatments were reported, if any.

On an unknown date in JUN-2025, the patient experienced Low sodium due to NATRILIX. They took the patient to the emergency room (she was only there for 1 day, the date was unknown).
Since unknown date, she experienced Worsening of Cholesterol problems. Her cholesterol problems had normalized, but she was prescribed with Rosuvastatin calcium 20mg again, he did not confirm specifically if she had problems with her cholesterol again. The intensity was not obtained
In unknown date, She was diagnosed with heart problems. He did not know how long ago, but it was while She was taking NATRILIX. heart problems treated with Ranolazine (1000 mg daily, oral) since unknown date.

Action taken regarding NATRILIX SR 1.5MG: Drug withdrawn, Since unknown date, patient stopped taking NATRILIX.

Outcome of Low sodium: Recovering
Outcome of Worsening of Cholesterol problems: Unknown
Outcome of Diagnostic of heart problems: Not recovered.

Reporter assessment : Not serious. Related for low sodium but causal relationship unknown for Worsening of Cholesterol problems and Diagnostic of heart problems.

Consent to contact the doctor was not obtained.
FU requested to the CRO with reporter.

Case Comment: Cardiac disorder and Worsening of blood cholesterol are unlisted while Blood sodium decreased is listed as per RSI of INDAPAMIDE 1.5MG-F37. Considering the medical history of cholesterol abnormal, unspecified heart disorder, known pharmacological plausibility for Blood sodium decreased with missing information (definitive therapy and event dates, investigations) the causal role is possible for Blood sodium decreased while unlikely for Cardiac disorder and Worsening of blood cholesterol.

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) INDAPAMIDE 1.5MG-F37 (INDAPAMIDE 1.5 mg) Coated tablet, 1.5 mg; Regimen #2	1.5 mg, qd; Oral use	Hypertension (Hypertension)	Unknown; Unknown