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		49 Years	Female	Unk			2023

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

Patient took a quarter tablet daily of NATRILIX SR 1.5MG by medical prescription [Prescribed underdose]

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).

(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

15. DAILY DOSE(S)
#1) 0.375 mg, qd

16. ROUTE(S) OF ADMINISTRATION
#1) Oral use

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

18. THERAPY DATES(from/to)
#1) 2023 / Ongoing

19. THERAPY DURATION
#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) Concor (Bisoprolol fumarate) ; 2020 / 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)

IV. MANUFACTURER INFORMATION

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

26. REMARKS
Patient ID: 108750823
Study ID: IC4-06520-001-CRI*

24b. MFR CONTROL NO.
S25011239

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:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The initial reporter was a Consumer.

The patient was a 49-year-old female (Height: 167 cm) with the medical history of Hypertension since 2010, treated with INDAPAMIDE 1.5MG-F37 (0.25 DF daily orally) since an unknown date in 2023, and Bisoprolol fumarate (2.5 mg daily, orally) from an unknown date in 2020.

No other concomitant treatment was reported, if any.

On an unknown date in 2023, the patient took a quarter tablet daily of INDAPAMIDE 1.5MG-F37 by medical prescription and and she did not experience any adverse event.

Action taken regarding INDAPAMIDE 1.5MG-F37: Dose not changed.

Outcome : Recovered (Special situation)

The reporter's assessment: Related. Not serious.

Consent to contact the doctor was not obtained.

CASE CLOSED.