SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET		
		Day	Month	Year				Day	Month	Year
PRIVACY	COSTA RICA		PRIVACY		35 Years	Male	Unk		Unk	

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

Nausea [Nausea]
Paresthesia was in all body [Paraesthesia generalised]

Case Description: This spontaneous case was received from a Physician in COSTA-RICA.

The patient was a 35-year-old male with an unspecified medical history was treated with NATRILIX SR 1.5MG (unknown daily dose) since an unknown date for an unknown indication.

(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) NATRILIX SR (INDAPAMIDE 1.5 mg) Coated tablet, 1.5 mg

15. DAILY DOSE(S)
#1) UNK

16. ROUTE(S) OF ADMINISTRATION
#1) Unknown

17. INDICATION(S) FOR USE
#1) (Product used for unknown indication)

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

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)

23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)
From/To Dates | Type of History / Notes | Description
Unknown

IV. MANUFACTURER INFORMATION

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

26. REMARKS

24b. MFR CONTROL NO.
S25006024

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

24c. DATE RECEIVED BY MANUFACTURER
24-JUN-2025

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

DATE OF THIS REPORT
08-JUL-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

No other concomitant medication was reported, if any

On an unknown date, the patient experienced nausea, and paresthesia was in all body.

On an unknown date, 3 days after discontinuation of NATRILIX SR 1.5MG, patient recovered.

On 24-JUN-2025, New information received from Physician: Through a duplicate of the case, physician detailed the event paresthesia was in all body.

Action taken regarding NATRILIX SR 1.5MG: Drug withdrawn.

Outcome: Recovered.

Reporter's causality assessment and event seriousness were not reported.

SIGNIFICANT FOLLOW-UP INFORMATION RECEIVED (24-JUN-2025): LLT was modified to Paraesthesia generalised for the PT "Paresthesia" in accordance with updated event verbatim and the narrative was updated accordingly.

Case Comment: Nausea and Paraesthesia are listed as per RSI of NATRILIX SR (INDAPAMIDE). Considering the known side effects, the positive dechallenge with missing information (medical history, definitive therapy and event dates, indication, investigations) the causal role is possible.