

# SUSPECT ADVERSE REACTION REPORT

## I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) <b>PRIVACY</b>	1a. COUNTRY <b>COSTA RICA</b>	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION  <input type="checkbox"/> PATIENT DIED  <input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION <input type="checkbox"/> INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY  <input type="checkbox"/> LIFE THREATENING <input type="checkbox"/> CONGENITAL ANOMALY  <input type="checkbox"/> OTHER
		Day	Month	Year	Unk	Unk	Unk	Day	Month	Year	
			<b>PRIVACY</b>						<b>Unk</b>		

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

Case Description: This is an spontaneous case received from a physician in COSTA-RICA.

The patient was an unknown year old of unknown gender with an unknown medical history treated with NATRILIX SR 1.5 mg (unknown daily dose) since an unknown date for an unknown indication.

No concomitant treatment was reported, if any.

(Continued on Additional Information Page)

## II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) <b>#1 ) NATRILIX SR (INDAPAMIDE 1.5 mg) Coated tablet, 1.5 mg</b>		20. DID REACTION ABATE AFTER STOPPING DRUG?  <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
15. DAILY DOSE(S) <b>#1 ) UNK</b>	16. ROUTE(S) OF ADMINISTRATION <b>#1 ) Unknown</b>	
17. INDICATION(S) FOR USE <b>#1 ) UNK (Product used for unknown indication)</b>		21. DID REACTION REAPPEAR AFTER REINTRODUCTION?  <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
18. THERAPY DATES(from/to) <b>#1 ) Unknown</b>	19. THERAPY DURATION <b>#1 ) Unknown</b>	

## 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 <b>Unknown</b>		

## IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER <b>Servier PANAMA COSTA RICA</b>		26. REMARKS
	24b. MFR CONTROL NO. <b>S25009758</b>	
24c. DATE RECEIVED BY MANUFACTURER <b>03-JUL-2025</b>	24d. REPORT SOURCE <input type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input checked="" type="checkbox"/> HEALTH PROFESSIONAL <input checked="" type="checkbox"/> OTHER: Spontaneous	
DATE OF THIS REPORT <b>21-JUL-2025</b>	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

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

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

On an unknown date the patient experienced Paresthesia.

Action taken regarding NATRILIX SR 1.5 mg : Unknown.

Outcome: Unknown

Reporter assessment was not provided.

Consent to contact the physician was obtained.

Case Comment: Paresthesia is listed in the RSI of NATRILIX SR. However, this case is poorly documented (missing information on chronology, medical history, concomitant drugs, action taken, outcome), a thorough case assessment and the causal role is assessed as considered.