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	GUATEMALA		PRIVACY		72 Years	Female	54.00 kg		MAY	2025

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

Leg swelling [Swelling of legs]
Fever [Fever]
General malaise [General malaise]
Pharmacy sold her INDAPAMIDE 1.5MG/AMLODIPINE 5MG-F-32 instead of Natrilix SR 1.5mg [Wrong drug product dispensed]
Pharmacy sold INDAPAMIDE 1.5MG/AMLODIPINE 5MG-F-32 instead of Natrilix SR 1.5mg and she took it [Wrong product administered]

Case Description: This solicited case was received from a Consumer regarding a patient participating in the study with protocol

(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/AMLODIPINE 5MG-F-32 (INDAPAMIDE 1.5 mg, AMLODIPINE 5 mg) Modified-release

(Continued on Additional Information Page)

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

17. INDICATION(S) FOR USE
#1) Heart failure (Cardiac failure)

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) MAY-2025 / JUN-2025	#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) Estradiol (Estradiol) 2 mg; 1990 / Ongoing

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

From/To Dates	Type of History / Notes	Description
2024 to Ongoing	Historical Condition	Heart failure (Cardiac failure)

IV. MANUFACTURER INFORMATION

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

26. REMARKS
Patient ID: 1841844361301
Study ID: IC4-05520-001-GTM*

24b. MFR CONTROL NO.
S25011446

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

24c. DATE RECEIVED BY MANUFACTURER
04-AUG-2025

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

DATE OF THIS REPORT
12-AUG-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

IC4-05520-001-GTM (Improve adherence to treatments) in GUATEMALA.

The patient was a 72 year-old female (patient ID: 1841844361301) (weight 54 kg, height 165 cm) with a medical history of Heart failure since 2024 treated with INDAPAMIDE 1.5MG/AMLODIPINE 5MG-F-32 (1 tablet daily, orally) from an unknown date in MAY-2025 to an unknown date in JUN-2025.

Concomitant treatment included Estradiol (2mg daily, oral) since 1990 as Hormones.

No other concomitant treatments were reported, if any.

From an unknown date in MAY-2025 to an unknown date in JUN-2025, the patient experienced medication error because the pharmacy sold her INDAPAMIDE 1.5MG/AMLODIPINE 5MG-F-32 instead of Natrilix SR 1.5 mg and she took it, the correct one was INDAPAMIDE 1.5MG/AMLODIPINE 5MG-F-32.

On an unknown date in MAY-2025, the patient experienced Leg swelling, Fever and general malaise due to medication error made by pharmacy. Her doctor told her that these events were for taking the wrong one and told her to start the Natrilix and the effects improved.

Action taken regarding INDAPAMIDE 1.5MG/AMLODIPINE 5MG-F-32: Discontinued, In Jun-2025, patient changed INDAPAMIDE 1.5MG/AMLODIPINE 5MG-F-32 to Natrilix SR 1.5mg, 1 tablet.

Outcome: Recovered on an unknown date in JUN-2025.

The reporter related the events Leg swelling, Fever and general malaise to INDAPAMIDE 1.5MG/AMLODIPINE 5MG-F-32.
Causality assessment is not applicable for Pharmacy sold her INDAPAMIDE 1.5MG/AMLODIPINE 5MG-F-32 instead of Natrilix SR 1.5mg and Pharmacy sold INDAPAMIDE 1.5MG/AMLODIPINE 5MG-F-32 instead of Natrilix SR 1.5mg and she took it.
The reporter's seriousness assessment was non serious for all events

Consent to contact the doctor was not obtained.
Case closed.

Case Comment: Pyrexia is unlisted while Peripheral swelling and Malaise are listed as per RSI of INDAPAMIDE 1.5MG/AMLODIPINE 5MG-F-32. Considering the compatible chronology, given the context of medication error, role of medical history with missing information (definitive therapy and event dates, investigations) the causal role is possible for Peripheral swelling and Malaise while unlikely for Pyrexia.

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/AMLODIPINE 5MG-F-32 (INDAPAMIDE 1.5 mg, AMLODIPINE 5 mg) Modified-release tablet; Regimen #1	1 DF, qd; Oral use	Heart failure (Cardiac failure)	MAY-2025 / JUN-2025; Unknown