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	GUATEMALA		PRIVACY		69 Years	Female	49.00 kg		FEB	2025

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

Thick blood [Blood viscosity increased]
Platelet problems [Platelet disorder]
Swollen ankles [Swollen ankles]
High blood pressure [Blood pressure high]
Sedimentation rate (high) [Sedimentation rate increased]
The patient stopped taking NATRILIX (as prescribed by her doctor) for a weekend (two days, no dates specified).

(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)

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

15. DAILY DOSE(S)
#1) 1.5 mg, qd

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

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

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

18. THERAPY DATES(from/to)
#1) 2007 / JUN-2025

19. THERAPY DURATION
#1) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) Aprovel (Irbesartan) ; 2010 / Ongoing

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

From/To Dates	Type of History / Notes	Description
2006 to Ongoing	Historical Condition	Hypertension (Hypertension)

IV. MANUFACTURER INFORMATION

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

26. REMARKS
Patient ID: 2572872051401
Study ID: IC4-06520-001-GTM*

24b. MFR CONTROL NO.
S25010040

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

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

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

DATE OF THIS REPORT
29-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

[Temporary interruption of therapy]

Case Description: This solicited case was received in GUATEMALA and concerned a patient participating in the post-authorization study (IC4-06520-001-GTM) (Improve adherence to treatments). The initial reporter was a Consumer.

The patient was a 69-year-old female (Weight: 49 kg, Height :147 cm) with the medical history of Hypertension since unknown date in 2006, treated with INDAPAMIDE 1.5MG-F37 (1 tablet daily, orally) from unknown date in 2007 to unknown date in JUN-2025, then (1 tablet daily, orally) since unknown date in JUN-2025 and Irbesartan (300 mg daily, orally) since unknown date in 2010.
No other concomitant treatment was reported, if any.

On unknown date in FEB-2025, the patient experienced Thick blood and a Platelet problem. The doctor told that INDAPAMIDE 1.5MG-F37 was probably causing these events and that it could cause blood clots or a stroke, so she stopped her from taking this medication but she didn't give her any other option, so she continued taking INDAPAMIDE 1.5MG-F37. She didn't know what the doctor based her opinion on, and she didn't give her any further explanation. The IGSS gave her a generic, not INDAPAMIDE 1.5MG-F37 but she didn't take it because she was allergic to it, so she always bought it. No intensity was obtained.

On unknown date in JUN-2025, the patient experienced Swollen ankles and High blood pressure. This happened because she stopped taking INDAPAMIDE 1.5MG-F37 (as prescribed by her doctor) for a weekend (two days, no dates specified), so she restarted the medication the following Monday and the symptoms disappeared. If she stopped taking INDAPAMIDE 1.5MG-F37 , these symptoms reappeared. No intensity was obtained.

On unknown date in JUN-2025, the patient experienced Sedimentation rate. On unknown date in JUN-2025, the patient had laboratory tests done like dimer and her hematologist told her that her blood was normal, only that she had a sedimentation rate. No intensity was obtained.

Treatment of Thick blood and Platelet problem: On unknown date in FEB-2025,the patient took blood thinning medication and an anticoagulant (name and doses not given).

Action taken with INDAPAMIDE 1.5MG-F37: Dose not changed.
Outcome: Recovered from Thick blood, Platelet problems, Swollen ankles and High blood pressure
Not recovered from sedimentation rate (high).

The case was reported as non-serious.
The reporter's causality assessment was related for thick blood, platelet problem, swollen ankles, high blood pressure and unknown for Sedimentation rate

Consent to contact the doctor was not obtained.

Follow-up with relative will be requested.

Case Comment: Blood viscosity increased, platelet disorder, joint swelling, hypertension and red blood cell sedimentation rate increased are unlisted in the RSI of INDAPAMIDE 1.5MG-F37. Given the recovery despite drug continuation, the causal role for Blood viscosity increased and platelet disorder is assessed as possible. Due to the onset during therapy interruption and recovery following drug resumption, the causal role is assessed as unlikely for joint swelling and hypertension. Based on the reasonable chronology and absence of recovery with drug continuation, the causal role for red blood cell sedimentation rate increased is assessed as possible.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	JUN-2025	Red blood cell sedimentation rate Positive		

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)	JUN-2025 / Ongoing; Unknown