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		101 Years	Female	54.00 kg		SEP	2024

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

Other Serious Criteria: Medically Significant
Heart problems [Heart disorder]
Brain oxygenation problems [Brain hypoxia]
Broke her hip [Hip fracture]
Fall [Fall]

Case Description: This solicited case was received from a Consumer in COSTA RICA and concerned a patient participating in the Patient Support Program IC4-06520-001-CRI (Improve patient adherence to the treatments).

(Continued on Additional Information Page)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☒ PATIENT DIED Date: 12-APR-2025
- ☐ 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
#2) Cardioaspirina (Acetylsalicylic acid)
(Continued on Additional Information Page)

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 1.5 mg, qd	#1) Oral use
#2) UNK	#2) Oral use

17. INDICATION(S) FOR USE
#1) Foot inflammation (Inflammation)
#2) To prevent the blood from thickening (Antiplatelet therapy)
(Continued on Additional Information Page)

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 2015 / SEP-2024	#1) Unknown
#2) 2005 / 12-APR-2025	#2) Unknown

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
2005 to 12-APR-2025	Historical Condition	Inflammation (Inflammation)
2005 to 12-APR-2025	Historical Condition	Rheumatoid arthritis (Rheumatoid arthritis)

IV. MANUFACTURER INFORMATION

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

26. REMARKS
Patient ID: 501420683
Study ID: IC4-06520-001-CRI*

24b. MFR CONTROL NO.
S25011355

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
05-AUG-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: S25011355

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The patient was a 101 year-old female (Weight: 54kg; Height: 163cm) with the medical history of Foot inflammation and rheumatoid arthritis since 2005, treated with INDAPAMIDE 1.5MG-F37 (1.5 mg Daily, orally) since unknown date in 2015 to unknown date in Sep-2024 then patient restarted the drug due to swelling in his arm, treated with INDAPAMIDE 1.5MG-F37 (1.5 mg daily, orally) since unknown date in Jan-2025 to 12-Apr-2025 and to prevent the blood from thickening since an unknown date, treated with ACETYLSALICYLIC ACID (Unknown daily dosage) since an unknown date in 2005 to 12-Apr-2025.

No other concomitant treatment was reported, if any.

On an unknown date in Sep-2024, she experienced Heart problems and she died because of this heart problems on 12-Apr-2025.

On 28-Jan unknown year, she experienced a fall and broke her hip.

On an unknown date, she experienced Brain oxygenation problems.

On an unknown date in 2019, the patient took Tomasina 500mg (1 DF Daily) as a treatment for brain oxygenation problems till 12-APR-2025.

Action taken with INDAPAMIDE 1.5MG-F37: Not applicable

Outcome: Fatal for Heart problems and brain oxygenation problems
Unknown for Fall and Hip fracture

Reporter assessment: Fall and hip fracture are assessed as not related. Heart problems and Brain oxygenation problems are assessed as unknown.

Case was reported as Serious (death).

Case Comment: Cardiac disorder, brain hypoxia, fall and hip fracture are all unlisted in the RSI of INDAPAMIDE. Given the reasonable chronology, medical history, and missing information (medical context, autopsy report), the causal role for cardiac disorder and brain hypoxia is assessed as possible. Based on the reasonable chronology, the causal role for fall is assessed as possible. Since hip fracture occurred following a fall, the reporter's opinion is maintained and the causal role is assessed as not related.

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 #1	1.5 mg, qd; Oral use	Foot inflammation (Inflammation) Rheumatoid arthritis (Rheumatoid arthritis) Swelling in his arm (Swelling)	2015 / SEP-2024; Unknown
#1) INDAPAMIDE 1.5MG-F37 (INDAPAMIDE 1.5 mg) Coated tablet, 1.5 mg; Regimen #2	1.5 mg, qd; Oral use	Foot inflammation (Inflammation) Rheumatoid arthritis (Rheumatoid arthritis) Swelling in his arm (Swelling)	JAN-2025 / 12-APR-2025; Unknown
#2) Cardioaspirina (Acetylsalicylic acid) ; Regimen #1	UNK; Oral use	To prevent the blood from thickening (Antiplatelet therapy)	2005 / 12-APR-2025; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown	Historical Condition	Swelling (Swelling);
Unknown	Historical Condition	Antiplatelet therapy (Antiplatelet therapy);