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		83 Years	Female	63.00 kg			2023

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

Knee wear [Unspecified disorder of knee joint]
Bone problems [Bone disorder NOS]
She took half a tablet of INDAPAMIDE 1.5MG-F37 in the morning and half a tablet in the afternoon [Drug use for unapproved dosing regimen]
She took half a tablet of INDAPAMIDE 1.5MG-F37 in the morning and half a tablet in the afternoon [Drug use for unapproved schedule]

Case Description: This solicited case was received in COSTA RICA and concerned a patient participating in the post-authorization study (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
- ☐ 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) she took ha (Continued on Additional Information Page)

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) 2023 / Unknown

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) Olmesartan (Olmesartan medoxomil) 40 mg; 2023 / Ongoing
#2) Carbimen (Lercanidipine hydrochloride) 20 mg; Ongoing
#3) Fluoxetina (Fluoxetine hydrochloride) 20 mg; 2024 / Ongoing
#4) Acetylsalicylic acid (Acetylsalicylic acid) ; 2021 / Ongoing
#5) Magnesio (Magnesium) ; 2005 / Ongoing
#6) Ginkgo biloba (Ascorbic acid, Cyanocobalamin, Folic acid, Ginkgo biloba,

(Continued on Additional Information Page)

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 Ongoing	Historical Condition	Hypertension (Hypertension)
Unknown to Ongoing	Historical Condition	

(Continued on Additional Information Page)

IV. MANUFACTURER INFORMATION

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

26. REMARKS
Patient ID: 500950894
Study ID: IC4-06520-001-CRI*

24b. MFR CONTROL NO.
S25011354

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

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

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

DATE OF THIS REPORT
15-AUG-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The initial reporter was a Consumer.

The patient was an 83-year-old female (weight: 63 kg) with a medical history of Hypertension since an unknown date, treated with INDAPAMIDE 1.5MG-F37 (1.5mg daily, orally half a tablet in the morning and a tablet at night), Olmesartan medoxomil (40mg daily, orally) both since an unknown date in 2023.
Concomitant treatments included Acetylsalicylic acid (1 DF Daily) since 2021 as Blood and heart attacks prevention, Fluoxetine hydrochloride (20mg daily) since an unknown date in 2024 as a tranquilizer, Magnesium (1 DF Daily) since an unknown date in 2005 and Ascorbic acid, Cyanocobalamin, Folic acid, Ginkgo biloba, Pyridoxine hydrochloride, Riboflavin, Vitamin b1 nos (One tablet occasionally) since an unknown date both as a Vitamin supplementation.
Concomitant drugs included Lercanidipine hydrochloride (unknown daily dose) since an unknown date for unknown indication.

No other concomitant treatment was reported if any.

On an unknown date in 2023, She took half a tablet of INDAPAMIDE 1.5MG-F37 in the morning and half a tablet in the afternoon, by medical prescription.
On an unknown date, the patient experienced knee wear and bone problems. The exact date of diagnosis has not been confirmed. The patient indicated that it was in 2022 and then indicated that it occurred while taking the medication NATRILIX SR 1.5 MG. This information cannot be confirmed, and the intensity of the event has not been determined.
On an unknown date in 2024, she took Alendronate 70 mg (1 tablet every 8 days) for bone problem as a treatment drug.

Action taken with INDAPAMIDE 1.5MG-F37: Unknown
Outcome: Not recovered for Bone problem and Knee wear.
Recovered for Drug prescribed in an unapproved dosage regimen and Drug use for unapproved schedule.

Reporter assessment : Not serious. Not related for Knee wear and Bone problems.
FU requested to the CRO

Case Comment: Arthropathy and bone disorder are unlisted as per INDAPAMIDE RSI. Considering the nature of the adverse events with limited information on time relationship, clinical context, medical intervention and action taken, the reporter's opinion was maintained, and causality was 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	she took half a tablet in the morning and a tablet at night; Oral use	Hypertension (Hypertension)	2023 / Unknown; Unknown

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION continued

#6) Ginkgo biloba (Ascorbic acid, Cyanocobalamin, Folic acid, Ginkgo biloba, Pyridoxine hydrochloride, Riboflavin, Vitamin b1 nos) ; 2024 / Ongoing

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Historical Condition	Cardiovascular event prophylaxis (Cardiovascular event prophylaxis);
Unknown to Ongoing	Historical Condition	Vitamin supplementation (Vitamin supplementation);