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		82 Years	Female	Unk		NOV	2024

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

Patient in bed [Bedridden]
Stopped walking [Unable to walk]
Chest pain [Chest pain]
Difficulty breathing [Difficulty breathing]
Memory problems [Memory impairment]

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). The initial reporter was a Consumer's relative.

(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
#2) VASTAREL 35 mg (TRIMETAZIDINE DIHYDROCHLORIDE 35 mg) Modified-release tablet, 35 mg

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) UNK	#1) Oral use
#2) 70 mg, qd	#2) Oral use

17. INDICATION(S) FOR USE
#1) (Product used for unknown indication)
#2) Heart problems (Cardiac disorder)

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) Unknown	#1) Unknown
#2) JAN-2025 / Ongoing	#2) 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)

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

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Historical Condition	Heart disease, unspecified (Cardiac disorder)
2005 to Ongoing	Historical Condition	Open heart surgery (Cardiac operation)

IV. MANUFACTURER INFORMATION

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

26. REMARKS
Patient ID: 102950838
Study ID: IC4-06520-001-CRI*

24b. MFR CONTROL NO.
S25009040

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

24c. DATE RECEIVED BY MANUFACTURER
23-JUN-2025

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

DATE OF THIS REPORT
27-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The patient was a 82-year-old female (Height: 170 cm) with the medical history of heart problems since an unknown date, treated with VASTAREL 35 mg (70 mg daily orally) since an unknown date in JAN-2025 to ongoing.

Other suspect treatment included: INDAPAMIDE 1.5MG-F37 (unknown daily dose) since an unknown date for an unknown indication.

Other medical history includes: Open heart surgery performed in 2005.

Historical drug included: Euten (unknown daily dosage and unknown diagnostic).

No other concomitant treatment was reported, if any.

On an unknown date in NOV-2024, patient was in bed.
On an unknown date in NOV-2024, patient stopped walking.
On an unknown date, patient experienced chest pain. patient indicated that before, it hurt less, but now when they stood her up to change her, it hurt more.
On an unknown date, patient experienced difficulty breathing.
On an unknown date, patient experienced memory problems.

Action taken regarding INDAPAMIDE 1.5MG-F37: Drug withdrawn.
Action taken regarding VASTAREL 35 mg: Dose not changed.

Outcome for patient in bed, chest pain, difficulty breathing, stopped walking: Not Recovered.
Outcome for event memory problems: Unknown.

The case was considered as Serious (Disability: patient in bed and stopped walking).

The reporter's assessment was not provided for patient in bed, chest pain, difficulty breathing, memory problems. Not related for patient stopped walking.

Consent to contact the doctor was not obtained.

Case Comment: Bedridden, gait instability, chest pain, dyspnoea and memory impairment are unlisted in the RSI of both INDAPAMIDE 1.5MG-F37 and VASTAREL 35 mg. For bedridden and gait instability, the causal of VASTAREL 35 mg is assessed as not related due to chronological incompatibility, and the causal role of INDAPAMIDE 1.5MG-F37 is assessed as possible. Due to the history of heart problems and the negative dechallenge, the causal role of both drugs is assessed as unlikely for chest pain and dyspnoea. Given the missing information (onset date and outcome), the causal role of both drugs for memory impairment is assessed as conditional.

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown	Historical Drug	Euten (Eutens); unknown daily dosage and unknown diagnostic