

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY COSTA RICA	2. DATE OF BIRTH			2a. AGE 82 Years	3. SEX Female	3a. WEIGHT Unk	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION Date: 07-JUL-2025 <input checked="" type="checkbox"/> PATIENT DIED <input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION <input checked="" type="checkbox"/> INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY <input type="checkbox"/> LIFE THREATENING <input type="checkbox"/> CONGENITAL ANOMALY <input type="checkbox"/> OTHER
		Day	Month	Year				Day	Month	Year	
			PRIVACY						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 passed away [Death NOS]
 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).
 (Continued on Additional Information Page)

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		20. DID REACTION ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO <input type="checkbox"/> NA
15. DAILY DOSE(S) #1) UNK #2) 70 mg, qd	16. ROUTE(S) OF ADMINISTRATION #1) Oral use #2) Oral use	
17. INDICATION(S) FOR USE #1) (Product used for unknown indication) #2) Heart problems (Cardiac disorder)		21. DID REACTION REAPPEAR AFTER REINTRODUCTION? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
18. THERAPY DATES(from/to) #1) Unknown #2) JAN-2025 / Ongoing	19. THERAPY DURATION #1) Unknown #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.) <table border="0"> <tr> <td>From/To Dates</td> <td>Type of History / Notes</td> <td>Description</td> </tr> <tr> <td>Unknown to Ongoing</td> <td>Historical Condition</td> <td>Heart disease, unspecified (Cardiac disorder)</td> </tr> <tr> <td>2005 to Ongoing</td> <td>Historical Condition</td> <td>Open heart surgery (Cardiac operation)</td> </tr> </table>			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)
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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 08-JUL-2025	24d. REPORT SOURCE <input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL <input type="checkbox"/> OTHER:			
DATE OF THIS REPORT 09-JUL-2025	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> FOLLOWUP: 1			

ADDITIONAL INFORMATION**7+13. DESCRIBE REACTION(S) continued**

The initial reporter was a Consumer's relative.

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.

On 07-JUL-2025, the patient passed away (Cause of death was not reported).

Action taken regarding INDAPAMIDE 1.5MG-F37: Drug withdrawn.

Action taken regarding VASTAREL 35 mg: Not applicable

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 and Death).

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.

SIGNIFICANT FOLLOW-UP INFORMATION (08-JUL-2025): New event "Death" added, Action taken with "VASTAREL 35 mg" updated and narrative updated.

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. In this case, no further information about the clinical circumstances leading to death is provided. The limited available information precludes an accurate case assessment.

23. OTHER RELEVANT HISTORY continued

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