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		59 Years	Female	78.00 kg	25	APR	2025

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

Felt strange [Feeling strange]
Very low heart rate [Heart rate low]
High blood pressure [Blood pressure high]

Case Description: This solicited case was received in COSTA RICA and concerned a patient participating in the post-authorization study (IC4-05150-001-CRI.) (Improve adherence to 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) BISOPROLOL 5-PERINDOPRIL ARGININE 10 (BISOPROLOL 5 mg, PERINDOPRIL ARGININE 10 mg) Tablet,
(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 DF, qd	#1) Oral use

17. INDICATION(S) FOR USE
#1) Keep the heart rate moderated (Heart rate abnormal)

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 23-APR-2025 / 27-APR-2025	#1) 5 days

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) Cardioaspirina (acetylsalicylic acid) ; Ongoing

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

From/To Dates	Type of History / Notes	Description
2024 to Unknown	Procedure	Heart valve replacement NOS (Heart valve replacement)
Unknown	Historical Drug via oral, 1 tablet daily	Enalapril 5mg (Enalapril)

IV. MANUFACTURER INFORMATION

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

26. REMARKS
Patient ID: 106680620
Study ID: IC4-05150-001-CRI*

24b. MFR CONTROL NO.
S25006160

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

24c. DATE RECEIVED BY MANUFACTURER
30-APR-2025

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

DATE OF THIS REPORT
08-MAY-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The initial reporter was a Consumer.

The patient was a 59-year-old female (Weight: 78 kg, Height: 163 cm) with the medical history of Valve replacement surgery in 2024, the patient was treated with BISOPROLOL 5-PERINDOPRIL ARGININE 10 (1 DF daily, orally) from 25-APR-2025 to 27-APR-2025 to maintain a moderate heart rate after the Valve replacement surgery.

The patient was previously on Enalapril 5mg (1 DF daily) between unknown date to unknown date for not reported diagnosis, Carvedilol 6.25mg (2 DF daily) between unknown date to unknown date for not reported diagnosis.

Concomitant drugs included acetylsalicylic acid (unknown dose daily, unknown administration route) since unknown date for unknown indication.

No other concomitant treatment was reported, if any.

On 25-APR-2025, she felt strange (she did not specify) and she began to notice that her heart rate was very low. Her cardiologist told her it was because of COSYREL, which didn't agree with. The intensity of the event was not obtained.
On 25-APR-2025, she experienced High blood pressure. Her cardiologist told her it was because of COSYREL, which didn't agree with. The intensity of the event was not obtained.
Since an unknown date, doctor changed BISOPROLOL 5-PERINDOPRIL ARGININE 10 to Coversyl 10mg, this one hasn't started yet.

Action taken regarding BISOPROLOL 5-PERINDOPRIL ARGININE 10: Drug withdrawn.
Outcome of She felt strange: unknown
Outcome of Very low heart rate: unknown
Outcome of High blood pressure: unknown.

Seriousness and causality assessment: Related, not serious.

Consent to contact the doctor was not obtained. FU requested to the reporter.

Case Comment: Feeling abnormal and heart rate decreased are listed according to the Reference Safety Information of COSYREL, while hypertension is unlisted. Considering compatible chronology, previous medical intervention (valve replacement surgery) and missing information on etiological investigation, the causal role is assessed as possible.

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) BISOPROLOL 5-PERINDOPRIL ARGININE 10 (BISOPROLOL 5 mg, PERINDOPRIL ARGININE 10 mg) Tablet, 5/10 mg; Regimen #1	1 DF, qd; Oral use	Keep the heart rate moderated (Heart rate abnormal)	23-APR-2025 / 27-APR-2025; 5 days

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown	Historical Drug via oral, 2 tablets daily	Carvedilol 6.25mg (Carvedilol);
Unknown to Ongoing	Historical Condition	Heart rate abnormal (Heart rate abnormal);