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		35 Years	Female	86.00 kg			2025

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

Dizziness [Dizziness]
She felt sick [Sickness]
Didn't find it in the pharmacy [Product availability issue]
COSYREL 5/10MG: Temporarily interrupted [Therapy interrupted]

Case Description: This solicited case was received from COSTA RICA and concerned a patient participating in the post-authorization study (IC4-05150-001-CRI) (Improve patient adherence to treatments). The initial reporter was a Consumer.

(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) Heart problems (Cardiac disorder)

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 2023 / 11-JUL-2025	#1) 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
2022 to Ongoing	Historical Condition	Heart disorder (Cardiac disorder)
2022 to Ongoing	Historical Condition	Fainting (Syncope)

IV. MANUFACTURER INFORMATION

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

26. REMARKS
Patient ID: 114520701
Study ID: IC4-05150-001-CRI*

24b. MFR CONTROL NO.
S25010304

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

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

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

DATE OF THIS REPORT
27-AUG-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The patient was a 35-year-old female (Weight: 86 kg, Height 164 cm) with the medical history of heart problems, treated with BISOPROLOL 5-PERINDOPRIL ARGININE 10 (1 DF daily, orally) from unknown date in 2023 to 11-JUL-2025, fainting and cannot walk all since unknown date in 2022.
No concomitant treatment was reported, if any.

On 12-JUL-2025, the patient experienced Dizziness and she felt sick like she was descomposed because she did not take the daily COSYREL 5/10MG tablet because she didn't find it in the pharmacy.
On 13-JUL-2025, the patient felt the same way, so his doctor told her to take Cosyrel 5/5mg for this month while she finds COSYREL 5/10MG.

Treatment of the reaction (Diagnostic of Dizziness and She felt sick)
On 13-JUL-2025, the doctor changed COSYREL 5/10 mg to Cosyrel 5/5 mg for a month.
Since 13-JUL-2025, the patient started taking Cosyrel 5/5mg, unknown dose daily.

On AUG-2025, the patient recovered from the events, those events were assessed as "mild intensity". She associated the events with BISOPROLOL 5 PERINDOPRIL ARGININE 10 because she didn't find it in the pharmacy.
On an unknown date, the patient returned to BISOPROLOL 5-PERINDOPRIL ARGININE 10.

Action taken with BISOPROLOL 5-PERINDOPRIL ARGININE 10: Not applicable (Temporarily interrupted because she didn't find it in the pharmacy).
Outcome: Recovered

The case was reported as non-serious.
The reporter's causality assessment was provided as related.

Consent to contact the doctor was not obtained.

SIGNIFICANT FOLLOW-UP INFORMATION (25-AUG-2025): Product tab updated (Dosage regimen added), Event tab updated (outcome of events Dizziness and felt sick changed from unknown to recovered , end date and reporter causality were added for events Dizziness and Felt sick) and Narrative updated.

Case Comment: Dizziness is listed while Illness is unlisted as per RSI of BISOPROLOL 5-PERINDOPRIL ARGININE 10. Considering the context of product availability issue with temporary interruption of therapy, recovery following drug resumption and missing information (therapy and event dates, investigations), 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	Heart problems (Cardiac disorder)	2023 / 11-JUL-2025; Unknown
#1) BISOPROLOL 5-PERINDOPRIL ARGININE 10 (BISOPROLOL 5 mg, PERINDOPRIL ARGININE 10 mg) Tablet, 5/10 mg; Regimen #2	1 DF, qd; Oral use	Heart problems (Cardiac disorder)	Ongoing; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
2022 to Ongoing	Historical Condition	Walking difficulty (Gait disturbance);