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		64 Years	Female	99.00 kg			2021

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

Fall [Fall]
Crooked leg, her leg twisted and the liquid spilled out [Twisted knee]
Fluid effusion from the leg [Effusion of lower leg joint]
Diagnostic of cholesterol problems [Blood cholesterol abnormal]
Worsening of memory problems [Memory disturbance] ([Condition worsened])
Headache [Headache]
Feel down [Feeling down]
Worsening of osteoporosis [Osteoporosis] ([Condition worsened])
Pharmacy sold her the wrong presentation of COSYREL (COSYREL 5/10MG) and she took it, the correct one was COSYREL 10/5MG.

(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 10-PERINDOPRIL ARGININE 5 (BISOPROLOL 10 mg, PERINDOPRIL ARGININE 5 mg) Tablet,
#2) COSYREL 5mg/10mg (BISOPROLOL 5 mg, PERINDOPRIL ARGININE **(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) UNK	#1) Oral use
#2) UNK	#2) Oral use

17. INDICATION(S) FOR USE
#1) Arrhythmia (Arrhythmia)
#2) Arrhythmia (Arrhythmia)

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 2020 / FEB-2025	#1) Unknown
#2) FEB-2025 / FEB-2025	#2) 8 days

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) Rosuvastatina (Rosuvastatina) ; 2021 / Ongoing
#2) Eutirox (Levothyroxine sodium) ; 2017 / Ongoing

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

From/To Dates	Type of History / Notes	Description
2015 to Ongoing	Historical Condition	Osteoporosis (Osteoporosis)
2017 to Ongoing	Historical Condition	Thyroid disorder NOS (Thyroid disorder)

IV. MANUFACTURER INFORMATION

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

26. REMARKS
Patient ID: 105420400
Study ID: IC4-05150-001-CRI*

24b. MFR CONTROL NO.
S25012121

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

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

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

DATE OF THIS REPORT
19-AUG-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

[Wrong drug strength dispensed]
Pharmacy sold her the wrong presentation of COSYREL (COSYREL 5/10MG) and she took it, the correct one was COSYREL 10/5MG. [Wrong drug strength administered]

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

The patient was a 64-year-old female (Weight: 99 kg, Height :158 cm) with the medical history of Arrhythmia since unknown date in 2020, treated with BISOPROLOL 10-PERINDOPRIL ARGININE 5 (unknown daily dose, orally) from an unknown date in 2020 to FEB-2025 and since FEB-2025 to ongoing, the patient was on COSYREL 5mg/10mg (unknown daily dose, orally) between from an unknown date in FEB-2025 to FEB-2025 (for 8 days). Cholesterol problems since an unknown date treated with Rovustatina (unknown daily dose) since an unknown date in 2021, Thyroid problems since an unknown date treated with Levothyroxine sodium (100 mcg per day) since an unknown date in 2017.

Other medical history included memory problems since an unknown date, Osteoporosis since 2015.

No other concomitant treatment was reported, if any.

On an unknown date in 2021, the patient was diagnosed with cholesterol problems. The intensity and to what she related it to were not obtained.

On an unknown date in 2024, the patient experienced a Worsening of Memory problems. It was not obtained to what she related it and intensity.

On an unknown date in FEB-2025 (8 days), patient experienced medication error because the pharmacy sold her the wrong presentation of COSYREL (COSYREL 5/10MG) and she took it, the correct one was COSYREL 10/5MG.

On an unknown date in FEB-2025, patient experienced a headache and she felt down (The intensity was not obtained) due to the error that the pharmacy had regarding the sale of the incorrect presentation.

On an unknown date in MAY-2025, patient had a worsening of osteoporosis. It was not obtained to what she related it. For this, the doctor prescribed APLASTA, however, this caused a reaction (no further information was obtained) and she was in bed.

On an unknown date in JUL-2025, patient experienced a Fall, her leg twisted and the liquid spilled out. She didn't know exactly what happened, but she was currently in bed. It was not obtained to what she related it and intensity.

Treatment of Worsening of osteoporosis: APLASTA (not reported dose).

Action taken with BISOPROLOL 10-PERINDOPRIL ARGININE 5: Dose not changed.
Action taken with COSYREL 5mg/10mg: Drug withdrawn.

Outcome of Diagnostic of Cholesterol problems, Worsening of Memory problems, Worsening of osteoporosis, Fall, Crooked leg, Fluid effusion from the leg : Not recovered

Outcome of Product dispensing error, headache, Feeling down: Recovered

The case was reported as serious for event Fall, Crooked leg, Fluid effusion from leg, APLASTA medication gave her reaction (Disability).

The reporter's causality assessment regarding BISOPROLOL 10-PERINDOPRIL ARGININE 5 was related for Headache, feeling down, Not related for Worsening of memory problems, Fall, Crooked leg, Fluid effusion from leg, not reported for Diagnostic of Cholesterol problem, Worsening of Osteoporosis, APLASTA medication gave her reaction (event was not considered by the MAH as it is related to APLASTA).
The reporter's causality assessment regarding COSYREL 5mg/10mg for headache was not reported.

Consent to contact the doctor was not obtained.

Case Comment: Fall, headache and and depressed mood are listed in COSYREL (BISOPROLOL, PERINDOPRIL) RSI, while other events are unlisted. Considering reasonable chronology, the causal role of COSYREL (5/10 MG and 10/5MG) was assessed as possible for headache. Given the patient's underlying diseases, the nature of the adverse events and lack of information on the circumstances surrounding the patient's falling incident, the causal role of COSYREL (10/5MG) for other adverse events appears unlikely. Product dispensing error with Incorrect dose administered were reported under COSYREL (5/10 MG).

Mfr. Control Number: S25012121

ADDITIONAL INFORMATION

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 10-PERINDOPRIL ARGININE 5 (BISOPROLOL 10 mg, PERINDOPRIL ARGININE 5 mg) Tablet, 10/5 mg; Regimen #1	UNK; Oral use	Arrhythmia (Arrhythmia)	2020 / FEB-2025; Unknown
#1) BISOPROLOL 10-PERINDOPRIL ARGININE 5 (BISOPROLOL 10 mg, PERINDOPRIL ARGININE 5 mg) Tablet, 10/5 mg; Regimen #2	UNK; Oral use	Arrhythmia (Arrhythmia)	FEB-2025 / Ongoing; Unknown
#2) COSYREL 5mg/10mg (BISOPROLOL 5 mg, PERINDOPRIL ARGININE 10 mg) Tablet, 5/10 mg; Regimen #1	UNK; Oral use	Arrhythmia (Arrhythmia)	FEB-2025 / FEB-2025; 8 days

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
2020 to Ongoing	Historical Condition	Arrhythmia (Arrhythmia);
Unknown to Ongoing	Historical Condition	Memory disturbance (Memory impairment);
Unknown to Ongoing	Historical Condition	Cholesterol (Blood cholesterol);