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		35 Years	Female	79.00 kg			2022

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

Patient took 1 tablet daily of TRIPLIXAM 10/2.5/10MG,1 tablet daily of TRIPLIXAM 5/1.25/5MG and 1 tablet daily of COSYREL 5/5MG by medical prescription [Prescribed overdose]
She did not experience any adverse events with the medications [No adverse event]

Case Description: This solicited case was received from a Consumer in COSTA RICA and concerned a patient participating in the post-authorization study IC4-06593-001-CRI (patient ID: 603880250) (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) PERINDOPRIL ARG 10 / INDA 2.5 / AMLO 10-F34 (PERINDOPRIL ARGININE 10 mg, INDAPAMIDE 2.5 mg,
#2) TRIPLIXAM 5mg/1.25mg/5mg (PERINDOPRIL ARGININE 5 mg, **(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
#2) 1 DF, qd	#2) Oral use

17. INDICATION(S) FOR USE
#1) Heart problems (Cardiac disorder)
#2) Heart problems (Cardiac disorder)

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 2022 / Ongoing	#1) Unknown
#2) 2022 / Ongoing	#2) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) Jardiance (Empagliflozin) ; 2022 / Ongoing
#2) Janumet (Metformin hydrochloride, Sitagliptin phosphate monohydrate) ; 2020 / Ongoing
#3) Vastarel (Trimetazidine hydrochloride) ; MAY-2025 / Ongoing

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

From/To Dates	Type of History / Notes	Description
2020 to Ongoing	Historical Condition	Hypertension (Hypertension)
2020 to Ongoing	Historical Condition	Diabetes (Diabetes mellitus)

IV. MANUFACTURER INFORMATION

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

26. REMARKS
Patient ID: 603880250
Study ID: IC4-06593-001-CRI*

24b. MFR CONTROL NO.
S25006631

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

24c. DATE RECEIVED BY MANUFACTURER
16-MAY-2025

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

DATE OF THIS REPORT
23-MAY-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

Mfr. Control Number: S25006631

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The patient was a 35-year-old female (Height: 160 cm and weight: 79 kg) with a medical history of heart problems since 2015 treated with PERINDOPRIL ARG 10 / INDA 2.5 / AMLO 10-F34 (1 tablet daily, orally), TRIPLIXAM 5mg/1.25mg/5mg (1 tablet daily, orally), both since an unknown date in 2022, COSYREL 5mg/5mg (1 tablet daily, orally) since an unknown date in NOV-2023. Diabetes since 2020 treated with Metformin hydrochloride, Sitagliptin phosphate monohydrate (1 tablet occasionally, orally) since unknown date in 2020, Empagliflozin (1 tablet daily, orally) since unknown date in 2022, Trimetazidine hydrochloride (35 mg daily, orally) since an unknown date in MAY-2025 used for unknown indication.

Other medical history included Hypertension since unknown date in 2020.

No other concomitant treatment was reported, if any.

On an unknown date in 2022, patient experienced prescribed overdose, she took 1 tablet daily of PERINDOPRIL ARG 10 / INDA 2.5 / AMLO 10-F34, 1 tablet daily of TRIPLIXAM 5mg/1.25mg/5mg and 1 tablet daily of COSYREL 5/5MG by medical prescription.

Patient did not experience any adverse events with the medications, on the contrary, her diagnostic of Heart Problems was under control.

Action taken with PERINDOPRIL ARG 10 / INDA 2.5 / AMLO 10-F34, TRIPLIXAM 5mg/1.25mg/5mg and COSYREL 5mg/5mg: Dose not changed.

Outcome: Recovered (Special situation).

The reporter causality was considered as Not applicable

Event seriousness was not reported.

SIGNIFICANT FOLLOW-UP INFORMATION (16-MAY-2025): Indication of Trimetazidine hydrochloride was updated, new event PT "No adverse event" was added and Narrative updated accordingly.

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) PERINDOPRIL ARG 10 / INDA 2.5 / AMLO 10-F34 (PERINDOPRIL ARGININE 10 mg, INDAPAMIDE 2.5 mg, AMLODIPINE 10 mg) Tablet, 10/2.5/10 mg; Regimen #1	1 DF, qd; Oral use	Heart problems (Cardiac disorder)	2022 / Ongoing; Unknown
#2) TRIPLIXAM 5mg/1.25mg/5mg (PERINDOPRIL ARGININE 5 mg, INDAPAMIDE 1.25 mg, AMLODIPINE 5 mg) Tablet, 5/1.25/5 mg; Regimen #1	1 DF, qd; Oral use	Heart problems (Cardiac disorder)	2022 / Ongoing; Unknown
#3) COSYREL 5mg/5mg (BISOPROLOL 5 mg, PERINDOPRIL ARGININE 5 mg) Tablet, 5/5 mg; Regimen #1	5 mg, qd (1 tablet daily); Oral use	Heart problems (Cardiac disorder)	NOV-2023 / Ongoing; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
2015 to Ongoing	Historical Condition	Heart disorder (Cardiac disorder);