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		87 Years	Female	49.00 kg			2018

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

Congestive heart failure [Congestive heart failure]
Regarding the diagnosis of arrhythmia, she had an episode of supraventricular tachycardia [Supraventricular tachycardia]

Case Description: This solicited case was received from a consumer's relative in COSTA RICA and concerned a patient participating in the post authorization study (IC4-06790-001-CRI) (Improve adherence to treatments).

The patient was an 87-year-old female (Weight: 49 kg, Height: 160 cm)

(Continued on Additional Information Page)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☒ PATIENT DIED Date: 29-MAY-2024
- ☐ 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) TRIMETAZIDINE 35MG-F31-A (TRIMETAZIDINE DIHYDROCHLORIDE 35 mg) Modified-release tablet, 35 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) 35 mg, qd	#1) Oral use

17. INDICATION(S) FOR USE
#1) Congestive heart failure (Cardiac failure congestive)
(Continued on Additional Information Page)

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) DEC-2023 / MAY-2024	#1) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) Bisoprolol fumarate (Bisoprolol fumarate) ; JUN-2023 / 29-MAY-2024
#2) Furosemida (Furosemida) ; 2020 / 29-MAY-2024

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

From/To Dates	Type of History / Notes	Description
2010 to 29-MAY-2024	Historical Condition	Hypertension (Hypertension)
2018 to 29-MAY-2024	Historical Condition	Congestive heart failure (Cardiac failure congestive)

IV. MANUFACTURER INFORMATION

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

26. REMARKS
Patient ID: 102550566
Study ID: IC4-06790-001-CRI*

24b. MFR CONTROL NO.
S25009155

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

24c. DATE RECEIVED BY MANUFACTURER
11-JUL-2025

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

DATE OF THIS REPORT
14-JUL-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

with the medical history of Congestive heart failure from unknown date in 2018 to 29-MAY-2024 and Heart problems since unreported date to 29-MAY-2024 both treated with TRIMETAZIDINE 35MG-F31-A (35 mg daily daily, orally) from unknown date in DEC-2023 to unknown date in MAY-2024,Hypertension from unknown date in 2010 to 29-MAY-2024, treated with Bisoprolol fumarate (5 mg daily, orally) from unknown date in JUN-2023 to 29-MAY-2024, Fluid retention since unknown date in 2020 to 29-MAY-2024, treated with Furosemida (60 mg daily, orally) from unknown date in 2020 to 29-MAY-2024.

Other medical history included: Heart Failure with reduced ejection fraction with signs of ischemic and hypertensive heart disease since an unknown date in DEC-2023 to 29-MAY-2024.

No other concomitant treatment was reported, if any.

On an unknown date, Echocardiogram results which showed Heart Failure with reduced ejection fraction with signs of ischemic and hypertensive heart disease.

On unknown date in DEC-2023, the patient had an episode of supraventricular tachycardia (diagnosis of arrhythmia). Causal relationship with Servier drug and the intensity of the event were not obtained. No information was obtained as to whether the event occurred before or after TRIMETAZIDINE 35MG-F31-A.
Treatment of the reaction of Arrhythmia, in JUN-2023, the patient took Amiodarona 20mg, 1 tablet daily,orally.
In 29-MAY-2024, the patient experienced a Death due to Congestive heart failure.

Action taken regarding TRIMETAZIDINE 35MG-F31-A: Not applicable
Outcome: Fatal.

The case was reported as serious (seriousness criteria: death)
The reporter's assessment: not related for death, unknown for Supraventricular tachycardia

Consent to contact the doctor was obtained.
Follow-up requested with the physician.

SIGNIFICANT FOLLOW UP INFORMATION (11-JUL-2025): Medical history updated, lab data added, drug stop date was updated, narrative updated accordingly. Even PT Aarrhythmia changed to Supraventricular tachycardia.

Case Comment: Cardiac failure congestive and arrhythmia are unlisted in the RSI of TRIMETAZIDINE 35MG-F31-A. Given the extensive cardiac history of the patients, both events are assessed as progression of her current medical condition. Hence, the causal role is assessed as unlikely.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	16-JAN-2024	Echocardiogram Heart Failure with reduced ejection fraction with signs of ischemic and hypertensive heart disease		

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) TRIMETAZIDINE 35MG-F31-A (TRIMETAZIDINE DIHYDROCHLORIDE 35 mg) Modified-release tablet, 35 mg; Regimen #1	35 mg, qd; Oral use	Congestive heart failure (Cardiac failure congestive) Heart problems (Cardiac disorder)	DEC-2023 / MAY-2024; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
2020 to 29-MAY-2024	Historical Condition	Fluid retention (Fluid retention);
DEC-2023 to 29-MAY-2024	Historical Condition	Heart failure with reduced ejection fraction (Heart failure with reduced ejection fraction); Heart Failure with reduced ejection fraction with signs of ischemic and hypertensive heart

ADDITIONAL INFORMATION

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
	disease.	
Unknown to 29-MAY-2024	Historical Condition	Heart disorder (Cardiac disorder);