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		64 Years	Female	78.00 kg	25	MAY	2025

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

High pulse [High pulse rate]
Very 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 (IC4-06790-001-CRI) (Improve adherence to the 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) TRIMETAZIDINE 35MG-F31-A (TRIMETAZIDINE DIHYDROCHLORIDE 35 mg) Modified-release tablet, 35 mg

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 35 mg, qd	#1) Oral use

17. INDICATION(S) FOR USE
#1) Gastric protector (Gastrointestinal disorder)

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) JUN-2024 / Ongoing	#1) Unknown

20. DID REACTION ABATE AFTER STOPPING DRUG?
☐ YES ☐ NO ☒ NA

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

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) Ciblex (Mirtazapine) ; DEC-2024 / Ongoing
#2) Plasil (Metoclopramide) ; DEC-2024 / Ongoing

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

From/To Dates	Type of History / Notes	Description
2013 to Ongoing	Historical Condition	Hypertension (Hypertension)
2010 to Ongoing	Historical Condition	Depression (Depression)

IV. MANUFACTURER INFORMATION

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

26. REMARKS
Patient ID: 105450814
Study ID: IC4-06790-001-CRI*

24b. MFR CONTROL NO.
S25007758

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

24c. DATE RECEIVED BY MANUFACTURER
02-JUN-2025

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

DATE OF THIS REPORT
05-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: S25007758

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The initial reporter was a Consumer.

The patient was an 64-year-old female (weight: 78 kg, height: 152 cm) with a medical history of and Depression since unknown date in 2010, was treated with Mirtazapine (0.5 DF daily) and Metoclopramide (1 DF daily), both since unknown date in DEC-2024 and Hypertension since unknown date 2013.

The patient was treated with TRIMETAZIDINE 35MG-F31-A (35 mg daily, orally) since unknown date in JUN-2024 for Gastric protector.

No other concomitant treatment was reported if any.

On 25-May-2025, the patient experienced Very high blood pressure and High pulse. The patient did not indicate if it is related to VASTAREL. The patient didn't know the intensity of the events, her pulse hadn't dropped, kept it at 101-110 beats per minute.
On 26-May-2025, the patient started taking Triplixam 5/1.25/5mg 1 tablet daily as treatment to reaction.

Actions taken regarding TRIMETAZIDINE 35MG-F31-A: Maintained.
Event Outcome: Recovered for Very high blood pressure and Not recovered for High pulse.

Seriousness assessment as per the reporter was not serious.

The reporter's causality assessment was not provided.

Case Comment: Hypertension is unlisted while Heart rate increased is listed as per RSI of VASTAREL (TRIMETAZIDINE). Considering the compatible chronology, history of hypertension, recovery of hypertension with antihypertensive agent with missing information (definitive therapy and event dates, investigations) the causal role is possible. Of note, VASTAREL was used in off label indication here.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	MAY-2025	Heart rate 101-110 beats per minute		100 60

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Historical Condition	Gastric disorder (Gastrointestinal disorder);