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		76 Years	Male	Unk	29	JUN	2025

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

The 75-year-old patient took 2 tablets of PROCOLARAN 5 mg daily by medical prescription [Drug use for unapproved dosing regimen]

Case Description: This solicited case was received from a Patient support program (IC4-16257-001-CRI) in COSTA RICA.

(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) IVABRADINE 5MG-F-42 (IVABRADINE) Film-coated tablet, 5 mg

15. DAILY DOSE(S)
#1) 10 mg, qd

16. ROUTE(S) OF ADMINISTRATION
#1) Oral use

17. INDICATION(S) FOR USE
#1) (Product used for unknown indication)

18. THERAPY DATES(from/to)
#1) 29-JUN-2025 / Ongoing

19. THERAPY DURATION
#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)

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

From/To Dates	Type of History / Notes	Description
2019 to Unknown	Historical Drug (6.25/7.5 mg) 2 tablets daily	Carivalan (Carivalan)

IV. MANUFACTURER INFORMATION

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

26. REMARKS
Patient ID: 800820379
Study ID: IC4-16257-001-CRI*

24b. MFR CONTROL NO.
S25009467

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
03-SEP-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The initial reporter was a consumer (Patient's relative).

The patient was a 76-year-old male with an unknown medical history.

The patient's historical treatment included Carivalan (6.25/7.5 mg) 2 tablets daily since unknown date in 2019.

The patient has been treated with IVABRADINE 5MG-F-42 (10 mg daily, orally) since 29-JUN-2025 for unknown indication.

No concomitant treatment was reported if any.

On an unknown date in 2019, the patient was previously taking two tablets of Carivalan 6.25/7.5 mg daily, but his doctor switched him to PROCOLARAN.
Since 29-JUN-2025, the patient took 2 tablets daily of IVABRADINE 5MG-F-42 (PROCOLARAN 5MG) by medical prescription.
Patient had no adverse events from taking 2 tablets of IVABRADINE 5MG-F-42 daily.

Action taken regarding IVABRADINE 5MG-F-42 : Dose not changed.
Outcome: Recovered (Special situation).

The reporter's seriousness assessment was not reported.
The reporter's causality assessment was not applicable.

Consent to contact the doctor was not obtained.
The patient did not provide any further information and hung up.

SIGNIFICANT FOLLOW-UP (25-AUG-2025): Patient age was updated and Narrative updated.