

1. PATIENT INITIALS (first, last)  PRIVACY	1a. COUNTRY  COSTA RICA	2. DATE OF BIRTH			2a. AGE  75 Years	3. SEX  Male	3a. WEIGHT  Unk	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION  <input type="checkbox"/> PATIENT DIED  <input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION <input type="checkbox"/> INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY  <input type="checkbox"/> LIFE THREATENING  <input type="checkbox"/> CONGENITAL ANOMALY  <input type="checkbox"/> OTHER
		Day	Month	Year			Day	Month	Year		
		PRIVACY	PRIVACY				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)											

14. SUSPECT DRUG(S) (include generic name) #1 ) IVABRADINE 5MG-F-42 (IVABRADINE) Film-coated tablet, 5 mg		20. DID REACTION ABATE AFTER STOPPING DRUG?  <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
15. DAILY DOSE(S) #1 ) 10 mg, qd	16. ROUTE(S) OF ADMINISTRATION #1 ) Oral use	21. DID REACTION REAPPEAR AFTER REINTRODUCTION?  <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
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	

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)

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. <b>S25009467</b>	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 30-JUN-2025	24d. REPORT SOURCE <input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL <input type="checkbox"/> OTHER:	
DATE OF THIS REPORT 11-JUL-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

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**ADDITIONAL INFORMATION****7+13. DESCRIBE REACTION(S) continued**

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

The patient was a 75 -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.

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.