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	HONDURAS		PRIVACY		10 Years	Male	56.00 kg			2021

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

Bradycardia [Bradycardia]
Headache [Headache]
Drug use in unapproved age group [Drug use in unapproved age group]

Case Description: This solicited case was received from HONDURAS and concerned a patient participating in the post-authorization study (IC4-16257-001-HND) (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) IVABRADINE 5MG-F-42 (IVABRADINE) Film-coated tablet, 5 mg
#2) PROCORALAN 7.5 mg (IVABRADINE) Film-coated tablet, 7.5 mg

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 5 mg, qd	#1) Oral use
#2) 15 mg, qd	#2) Unknown

17. INDICATION(S) FOR USE
#1) Tachycardia (Tachycardia)
#2) Tachycardia (Tachycardia)

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 2021 / JUN-2024	#1) Unknown
#2) JUN-2024 / Ongoing	#2) 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
2014 to Ongoing	Historical Condition	Tachycardia (Tachycardia)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
SERVIER CENTRO AMERICA Y CARIBE
PANAMA

26. REMARKS
Patient ID: 0510201100264
Study ID: IC4-16257-001-HND*

24b. MFR CONTROL NO.
S25009149

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

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

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

DATE OF THIS REPORT
22-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The initial reporter was a Consumer's relative.

This patient was a 10-year-old male (Weight: 56 kg, Height: 172 cm) with the medical history of Tachycardia since 2014, treated with IVABRADINE 5MG-F-42 (5 mg daily, orally) from unknown date in 2021 to unknown date in JUN-2024 and then PROCORALAN 7.5 mg (15 mg daily) since unknown date in JUN-2024.

Age of patient, the age reported is the age when the occurrence of first adverse event. Patient was born in 18-APR-2011 and now 14 years-old.

No concomitant treatment was reported, if any.

On unknown date in 2021, the minor patient started taking 1 tablet daily of IVABRADINE 5MG-F-42.
On unknown date in JUN-2024, the patient took 2 tablets of PROCOLARAN 7.5MG by medical prescription.
On unknown date in JUN-2024, the patient experienced bradycardia and headache due to PROCORALAN 7.5 mg.

Action taken with IVABRADINE 5MG-F-42: Drug withdrawn.
Action taken with PROCORALAN 7.5 mg: Dose not changed
Outcome: Recovered (special situation).
Recovered for Bradycardia and headache.

The case was reported as non-serious.

The reporter's causality assessment was not reported.

Consent to contact the doctor was not obtained.

Follow-up requested.

SIGNIFICANT FOLLOW UP INFORMATION (09-JUL-2025): New events "Bradycardia" and "Headache" were added. Narrative updated accordingly.

Case Comment: Bradycardia and Headache are listed as per RSI of PROCORALN (IVABRADINE). Considering the known side effect, recovery despite of ongoing PROCORALAN with missing information (definitive therapy and event dates, investigations) the causal role is possible. Of note, PROCORALAN was used in unapproved age group here.