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	GUATEMALA		PRIVACY		70 Years	Male	120.00 kg	22	APR	2025

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

Death due to not reported cause [Death NOS]

Case Description: This solicited case was received from a relative of a Consumer in the GUATEMALA and concerned a patient participating in the Patient Support Program (PSP) (IC4-06520-001-GTM) (Improve adherence to treatments).

The patient was a 70-year-old male (weight: 120 kg), with medical history of Heart problems, Cardiac arrhythmias and Hypertension from an unknown date to 22-APR-2025.

(Continued on Additional Information Page)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☒ PATIENT DIED Date: 22-APR-2025
- ☐ 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) INDAPAMIDE 1.5MG-F37 (INDAPAMIDE 1.5 mg) Coated tablet, 1.5 mg

15. DAILY DOSE(S)
#1) 1 DF, 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) 2015 / 22-APR-2025

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)
#1) Atlansil (Amiodarone) ; 2015 / 22-APR-2025
#2) Betaloc (Metoprolol tartrate) ; 2015 / 22-APR-2025
#3) Exforge (Amlodipine besilate, Valsartan) ; Unknown / 22-APR-2025

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

From/To Dates	Type of History / Notes	Description
Unknown to 22-APR-2025	Historical Condition	Hypertension (Hypertension)
Unknown to 22-APR-2025	Historical Condition	Cardiac arrhythmia (Arrhythmia)

IV. MANUFACTURER INFORMATION

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

26. REMARKS
Study ID: IC4-06520-001-GTM*

24b. MFR CONTROL NO.
S25011293

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

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

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

DATE OF THIS REPORT
04-AUG-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The patient has been treated with INDAPAMIDE 1.5MG-F37 (1 tablet daily, orally), Amiodarone (200 mg daily, orally), Metoprolol tartrate (100 mg daily, orally), all since unknown date in 2015 to 22-APR-2025, Amlodipine besilate, Valsartan (unknown daily dose), since an unknown date to 22-APR-2025, all used for an unknown indication.

No other concomitant treatment was reported if any.

On 22-APR-2025, patient experienced death due to not reported cause. Relative did not know if he related the death to the INDAPAMIDE 1.5MG-F37.

Action taken regarding INDAPAMIDE 1.5MG-F37: Not applicable.

Outcome: Fatal.

Reporter's causality assessment was not reported.

The case was reported as Serious (Seriousness criteria: Death).

Consent to contact the doctor was not obtained.

Case closed.

Case Comment: Death is considered an outcome. In this case, no further information about the clinical circumstances leading to death is provided. The limited available information precludes an accurate case assessment.

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to 22-APR-2025	Historical Condition	Heart disorder (Cardiac disorder);