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	GUATEMALA		PRIVACY		66 Years	Male	81.00 kg		APR	2025

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

Other Serious Criteria: Medically Significant
Diabetic coma [Diabetic coma]
Deafness [Deafness]

Case Description: This solicited case was received from a Consumer and concerned a patient participating in the patient support program with protocol IC4-05985-001-GTM (Improve adherence to treatments) in GUATEMALA.

The patient was a 66-year-old male (weight 81 kg, height 176 cm) with a

(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) PERINDOPRIL ARGININE 5-AMLODIPINE 5-F31 (PERINDOPRIL ARGININE 5 mg, AMLODIPINE 5 mg) Tablet,

(Continued on Additional Information Page)

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

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

17. INDICATION(S) FOR USE
#1) Hypertension (Hypertension)

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 2021 / JUN-2025	#1) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) Metformina (Metformin hydrochloride) ; JUN-2025 / Unknown

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

From/To Dates	Type of History / Notes	Description
2008 to Ongoing	Historical Condition	Hypertension (Hypertension)
2017 to Ongoing	Historical Condition	Diabetes (Diabetes mellitus)

IV. MANUFACTURER INFORMATION

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

26. REMARKS
Patient ID: 1953053961906
Study ID: IC4-05985-001-GTM*

24b. MFR CONTROL NO.
S25011287

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

24c. DATE RECEIVED BY MANUFACTURER
12-AUG-2025

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

DATE OF THIS REPORT
14-AUG-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: S25011287

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

medical history of Hypertension since 2008 treated with PERINDOPRIL ARGININE 5-AMLODIPINE 5-F31 (1 DF daily, orally) since unknown date in 2021 to unknown date in JUN-2025 and Diabetes since 2017 treated with Metformin hydrochloride (1000 mg daily) since unknown date in JUN-2025.

No other concomitant treatments were reported.

Since Apr-2025, patient experienced Deafness. He related it to other things (not for PERINDOPRIL ARGININE 5-AMLODIPINE 5-F31), but which ones were not obtained.

In Jun-2025, patient experienced a Diabetic coma. Due to this condition, he was ill and suffered a relapse (he referred to a diabetic coma). He was hospitalized for one month (dates were not obtained).

Action taken regarding PERINDOPRIL ARGININE 5-AMLODIPINE 5-F31: Discontinued, In Jun-2025, the doctor suspended PERINDOPRIL ARGININE 5-AMLODIPINE 5-F31.

Outcome: Recovering.

Causality assessment was not related for both events.

Seriousness was reported as Serious (hospitalization) for Diabetic coma and non-serious for Deafness.

Consent to contact the doctor was not obtained.

Case closed.

SIGNIFICANT FOLLOW UP INFORMATION RECEIVED (12-AUG-2025): The country of incidence was changed from "ANTIGUA AND BARBUDA" to "GUATEMALA" and Narrative updated accordingly.

Case Comment: Diabetic coma and deafness are unlisted in the RSI of PERINDOPRIL ARGININE 5-AMLODIPINE 5-F31. Given the reasonable chronology and positive dechallenge, but nature of the events, medical history and missing information (etiological test), the causal role is assessed as possible.

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#1) PERINDOPRIL ARGININE 5-AMLODIPINE 5-F31 (PERINDOPRIL ARGININE 5 mg, AMLODIPINE 5 mg) Tablet, 5/5 mg; Regimen #1	1 DF, qd; Oral use	Hypertension (Hypertension)	2021 / JUN-2025; Unknown