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		71 Years	Female	Unk		JAN	2025

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

Prefrontal cortex dysfunction [Central nervous system disorder]

Case Description: This solicited case was received from Consumer concerning a patient participating in the Patient Support Program (protocol IC4-06590-001-HND) (Improve adherence to treatments) in HONDURAS.

(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 ARG 5MG/INDAPAMIDE 1.25-F31 (PERINDOPRIL ARGININE 5 mg, INDAPAMIDE 1.25 mg)
(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) Eye pressure (Intraocular pressure test abnormal)

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 2015 / Ongoing	#1) Unknown

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
Unknown to Ongoing	Historical Condition	
Unknown to Ongoing	Historical Condition	Myopia (Myopia)

(Continued on Additional Information Page)

IV. MANUFACTURER INFORMATION

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

26. REMARKS
Study ID: IC4-06590-001-HND*

24b. MFR CONTROL NO.
S25009243

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

24c. DATE RECEIVED BY MANUFACTURER
26-JUN-2025

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

DATE OF THIS REPORT
03-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The patient was a 71-year-old female with a medical history of Eye pressure since unknown date treated with PERINDOPRIL ARG 5MG/INDAPAMIDE 1.25-F31 (1 DF daily, oral) since unknown date in 2015 and Myopia since childhood.

No other concomitant treatments were reported, if any.

In Jan-2025, patient was diagnosed with prefrontal cortex dysfunction. Physically, she was active, but not as much in the areas of logic, idea processing, or memory; she relied on her family.

Her relatives began noticing this condition two years ago (2023), but they thought it was the pandemic, the fact that they had been confined, until her doctor gave her the diagnosis. She did not know if this diagnostic was due PERINDOPRIL ARG 5MG/INDAPAMIDE 1.25-F31.

Treatment of the reaction (Diagnostic prefrontal cortex dysfunction): In Jan-2025 patient took Octanoic acid supplement, 5 tablets daily, orally and Optimal Carnivore Beef Organ supplement, 3 tablets daily, orally.

Action taken with PERINDOPRIL ARG 5MG/INDAPAMIDE 1.25-F31: Dose not changed.

Outcome of Diagnostic prefrontal cortex dysfunction: Not recovered.

Causality assessment was not reported.

Event was reported as serious (Disability).

Consent to contact the doctor was not obtained.

Case Comment: Nervous system disorder is unlisted as per RSI of PERINDOPRIL ARG 5MG/INDAPAMIDE 1.25-F31. Considering the advanced age of patient with missing information (definitive therapy and event dates, detailed neurological investigations) the causal role is possible. Of note, PERINDOPRIL ARG 5MG/INDAPAMIDE 1.25-F31 was given in off label indication here.

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 ARG 5MG/INDAPAMIDE 1.25-F31 (PERINDOPRIL ARGININE 5 mg, INDAPAMIDE 1.25 mg) Film-coated tablet, 5-1.25 mg; Regimen #1	1 DF, qd; Oral use	Eye pressure (Intraocular pressure test abnormal)	2015 / Ongoing; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Historical Condition	Intraocular pressure abnormal (Intraocular pressure test abnormal);