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	HONDURAS		PRIVACY		Unk	Male	Unk		Unk	

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

Heart problems [Heart disorder]

Case Description: This solicited case was received from a Consumer in HONDURAS and concerned a patient (ID: 020301200600036) participating in the Patient Support Program (PSP) (IC4-05985-001-HND) [Improve adherence to treatments].

The patient was an unknown age male with a unspecified medical history was treated with PERINDOPRIL ARGININE 3.5-AMLODIPINE 2.5-F40 (unknown daily dose, orally) since unknown date for unknown diagnosis and

(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 3.5-AMLODIPINE 2.5-F40 (PERINDOPRIL ARGININE 3.5 mg, AMLODIPINE 2.5 mg)
#2) LIPOROSA 10mg/10mg (Rosuvastatin zinc 10 mg, EZETIMIBE 10 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) UNK	#1) Oral use
#2) UNK	#2) Oral use

17. INDICATION(S) FOR USE
#1) (Product used for unknown indication)
#2) (Product used for unknown indication)

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) Ongoing	#1) Unknown
#2) Ongoing	#2) 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

IV. MANUFACTURER INFORMATION

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

26. REMARKS
Patient ID: 020301200600036
Study ID: IC4-05985-001-HND*

24b. MFR CONTROL NO.
S25010938

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

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

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

DATE OF THIS REPORT
07-AUG-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: S25010938

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

LIPOROSA 10mg/10mg (unknown daily dose, orally) since unknown date for unknown diagnosis.

No other concomitant treatments were reported, if any.

On an unknown date, the patient experienced Heart problems. He did not know if this diagnosis happened after or before PERINDOPRIL ARGININE 3.5-AMLODIPINE 2.5-F40 and LIPOROSA 10mg/10mg. The intensity of the event was not obtained.

Action taken regarding PERINDOPRIL ARGININE 3.5-AMLODIPINE 2.5-F40 and LIPOROSA 10mg/10mg: Dose not changed (maintained)

Outcome of Heart problems: Not recovered.

The reporter’s causality and the seriousness assessment were not provided by the reporter.

The patient did not want to provide more information. Consent to contact the doctor was not obtained.

Case Comment: Cardiac disorder is unlisted as per RSI of COVERAM (PERINDOPRIL ARGININE 3.5 mg, AMLODIPINE 2.5 mg) and LIPCOMB (Rosuvastatin zinc 10 mg, EZETIMIBE 10 mg). Considering the given details with missing information (medical history, indication, therapy and event dates, outcome, investigations) the causal role is unassessable.

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 3.5-AMLODIPINE 2.5-F40 (PERINDOPRIL ARGININE 3.5 mg, AMLODIPINE 2.5 mg) Tablet; Regimen #1	UNK; Oral use	(Product used for unknown indication)	Ongoing; Unknown
#2) LIPOROSA 10mg/10mg (Rosuvastatin zinc 10 mg, EZETIMIBE 10 mg) Capsule, hard, 10/10 mg; Regimen #1	UNK; Oral use	(Product used for unknown indication)	Ongoing; Unknown