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		74 Years	Female	81.00 kg		FEB	2025

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

Worsening cataract [Cataract aggravated]
Worsening dirty eyes [Eye discharge]
Worsening dirty eyes [Condition worsened]
Patient experienced Tight chest, she went to the doctor and was diagnosed with clogged arteries [Arterial occlusion NOS]

Case Description: This solicited case was received from a Consumer in HONDURAS and concerned a patient (ID: 0801195003595) participating in the post authorization study IC4-97009-001-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) LIPOROSA 10mg/10mg (Rosuvastatin zinc 10 mg, EZETIMIBE 10 mg) Capsule, hard, 10/10 mg
#2) LIPOROSA 20mg/10mg (Rosuvastatin zinc 20 mg, EZETIMIBE 10 mg) Capsule, hard, 20/10 mg

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

17. INDICATION(S) FOR USE
#1) Fatty liver (Hepatic steatosis)
#2) Fatty liver (Hepatic steatosis)

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) NOV-2024 / MAR-2025	#1) Unknown
#2) MAR-2025 / 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)
#1) Colmibe (Atorvastatin calcium, Ezetimibe) ; Ongoing
#2) Codiovan (Hydrochlorothiazide, Valsartan) ; Ongoing
#3) Isoptin (Verapamil) ; 1985 / Ongoing
#4) Galvus met (Metformin hydrochloride, Vildagliptin) ; Ongoing
#5) Eutirox (Levothyroxine sodium) ; Ongoing

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

From/To Dates	Type of History / Notes	Description
2022 to Ongoing	Historical Condition	Fatty liver (Hepatic steatosis)
1990 to Ongoing	Historical Condition	Hypertension (Hypertension)

IV. MANUFACTURER INFORMATION

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

26. REMARKS
Patient ID: 0801195003595
Study ID: IC4-97009-001-HND*

24b. MFR CONTROL NO.
S25007687

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

24c. DATE RECEIVED BY MANUFACTURER
30-MAY-2025

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

DATE OF THIS REPORT
06-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The patient was a 74-year-old female with a medical history of Fatty liver since 2022, treated with LIPOROSA 10mg/10mg (1 DF daily, orally) since an unknown date in Nov-2024 to unknown date in Mar-2025, LIPOROSA 20mg/10mg (1 DF Daily, orally) since unknown date in Mar-2025 and Atorvastatin calcium, Ezetimibe (unknown daily dose, orally) since unknown date, Hypertension since 1990, treated with Hydrochlorothiazide, Valsartan (1 DF Daily, orally) since unknown date and Verapamil (240 mg daily, orally) since unknown date in 1985, Diabetes since 2009, treated with Metformin hydrochloride, Vildagliptin (2 DF Daily, orally) since unknow date and Thyroid problems since 2015, treated with Levothyroxine sodium (1 DF Daily, orally) since unknown date.

Other medical histories included: Cataract since unknown date in NOV-2022 and dirty eyes since unknown date in 2022.

The patient's past drug history included Colmibe 10/10mg (Not reported dose) since not reported date for Fatty liver.

No other concomitant treatments were reported, If any.

On an unknown date in Feb-2025, the patient experienced cataract in one of her eyes.

On an unknown date in Nov-2024, the patient was diagnosed (before LIPOCOMB) but had worsened since Feb-2025. patient did not indicate the intensity.

On an unknown date in Feb-2025, the patient experienced Dirty eyes. the patient woke up with dirty eyes and this caused her a lot of itching. the patient was diagnosed in 2022 (before LIPOCOMB) but had worsened since Feb-2025, the patient did not indicate the intensity.

On an unknown date in Mar-2025, the patient experienced Tight chest, she went to the doctor and was diagnosed with clogged arteries. The intensity of the events was not obtained, the patient did not know if it was due to LIPOCOMB.

Treatment of the reaction (clogged arteries): In Mar-2025 the patient took VASTAREL LP 80mg 1 tablet daily

Action taken regarding LIPOCOMB 10MG/10MG: Discontinued. In Mar-2025 she changed it to LIPOCOMB 20MG/10MG.
Action taken regarding LIPOCOMB 20MG/10MG: Maintained

Outcome of the worsening cataract: Not recovered
Outcome of the worsening Dirty eyes: Not recovered
Outcome of the clogged arteries: Not recovered

Reporter assessment: causality not reported, not serious.

FU requested to the patient.

Case Comment: Cataract, Eye discharge and Arterial occlusive disease are unlisted as per RSI of LIPOCOMB (Rosuvastatin zinc, EZETIMIBE). Considering the advanced age of patient, nature of event the causal role is unlikely while possible for Arterial occlusive disease. Further the role of missing information (detailed investigation, definitive therapy and event dates) should be considered while assessing the case.

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
2009 to Ongoing	Historical Condition	Diabetes (Diabetes mellitus);
2015 to Ongoing	Historical Condition	Thyroid disorder NOS (Thyroid disorder);
Unknown	Historical Drug indication : fatty liver	Colmibe 10/10mg (Colmibe);
NOV-2024 to Ongoing	Historical Condition	Cataract (Cataract);
2022 to Ongoing	Historical Condition	Eye discharge (Eye discharge);