SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year			Day	Month	Year	
	Spain					Female	27	Oct	2023	☐ PATIENT DIED

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

Other Seriousness Criteria: Medically Significant
#1| Dolor [Pain] |

This case has been downloaded from the EudraVigilance database without narrative (L2A). (WWID: ES-AEMPS-1604730)

New version is created due to there is information not extracted (mapped) from database to the fields in the CIOMS:
Adult
Patient's weight and height: 60kg, 158cm
ALZIL PLUS 5 MG/10 MG COMPRIMIDOS RECUBIERTOS CON PELICULA, 30 comprimidos, action taken: withdrawn

/...continued

☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
☐ INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY
☐ LIFE THREATENING
☐ CONGENITAL ANOMALY
☒ OTHER

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1| ALZIL PLUS | Rosuvastatin + Ezetimibe | Film-coated tablet | Unknown {Lot#: 233959}
#3| Cardyl | Atorvastatin calcium | Unknown | Unknown {Lot#: HG0400}

20 DID REACTION ABATE AFTER STOPPING DRUG?

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1| 1/24	#1| Oral
#3| 1/24	#3| Oral

#1| ☐ YES ☐ NO ☐ NA
#3| ☐ YES ☐ NO ☐ NA

17. INDICATION(S) FOR USE
#1| Asked But Unknown
#3| Asked But Unknown

21. DID REACTION REAPPEAR AFTER REINTRODUCTION?

18. THERAPY DATES (from/to)	19. THERAPY DURATION
#1| 06-Nov-2023 to 10-Nov-2023	#1| 5.0 [Day]
#3| 19-Oct-2023 to 04-Nov-2023	#3| 17.0 [Day]

#1| ☐ YES ☐ NO ☐ NA
#3| ☐ YES ☐ NO ☐ NA

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#2| Nustendi | Bempedoic acid, Ezetimibe | 1/24 | Oral | 29-Feb-2024 to 12-Sep-2024

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

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
FERRER INTERNACIONAL, S.A.
Diagonal Avenue 549, 08029, Barcelona, Spain
Phone: +34936003700,

26. REMARKS
Company Comments: ID: 20-24-ESP-FER-0000629
Pain is expected according to the reference safety document of Rosuvastatin/Ezetimibe. This adverse reaction was involved in a serious case due to other medically important condition. The intensity of the adverse reaction was unknown. The suspected drug was withdrawn and the event recovered. Statin side effects can vary between different statins, but common side effects include headache, dizziness, gastrointestinal disorders or myalgias. In this particular case the temporal association, the positive withdrawn and the well-known pharmaco-toxicologic profile of the product could enhance the causal relationship. It is noteworthy to point that other suspected drug (Atorvastatin) could be also involved in the onset of the event. Further information should be needed to make a clear medical assessment and to investigate other ethiologies. In summary, based on the information provided, the Company assessed as possible the causal relationship between the drug and the event according to the Karch- Lasagna method.

24b. MFR CONTROL NO.
20-24-ESP-FER-0000629

25b. NAME AND ADDRESS OF REPORTER
Spain
Consumer

24c. DATE RECEIVED BY MANUFACTURER
10-Dec-2024

24d. REPORT SOURCE
☐ STUDY ☐ LITERATURE
☐ HEALTH PROFESSIONAL ☒ OTHER: Consumer (including Attorneys)

DATE OF THIS REPORT

25a. REPORT TYPE

14-May-2025	☐ INITIAL	☒ FOLLOWUP: 1	

ADDITIONAL INFORMATION

7+13 DESCRIBE REACTION(S) continued

NUSTENDI 180 mg/10 mg COMPRIMIDOS RECUBIERTOS CON PELICULA, 28 comprimidos, action taken: withdrawn; indication: Cholesterol high

CARDYL 20 mg COMPRIMIDOS RECUBIERTOS CON PELICULA, 28 comprimidos, action taken: withdrawn; indication: Cholesterol high

Outcome: recovered/resolved with sequelae; end date of the reaction: 03Dec2024