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				60 Years	Male	2	Aug	2023	☐ PATIENT DIED
										☒ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
										☐ INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY
										☐ LIFE THREATENING
										☐ CONGENITAL ANOMALY
										☐ OTHER

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

#1| Immune-mediated necrotising myopathy [Immune-mediated myositis] |

This case has been downloaded from the EudraVigilance database without narrative (L2A)(WWID:ES-AEMPS-1480356).

New version is created due to there is information not extracted (mapped) from database to the fields in the CIOMS:

ROSUVASTATINA/EZETIMIBA 10 mg/10 mg 30 comprimidos, action taken: withdrawn
Outcome of the reaction: not recovered/not resolved/ongoing: end date of the reaction: Asked But Unknown

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1| Rosuvastatin + Ezetimibe | Rosuvastatin + Ezetimibe | Unknown | Unknown {Lot#: Unknown}

20 DID REACTION ABATE AFTER STOPPING DRUG?
#1| ☐ YES ☐ NO ☐ NA

15. DAILY DOSE(S)
#1| 1 {DF} every 24 hour (0-0-1)

16. ROUTE(S) OF ADMINISTRATION
#1| Oral

17. INDICATION(S) FOR USE
#1| Hypercholesterolaemia [Hypercholesterolaemia]

21. DID REACTION REAPPEAR AFTER REINTRODUCTION?
#1| ☐ YES ☐ NO ☐ NA

18. THERAPY DATES (from/to)
#1| 26-Jun-2023 to 04-Aug-2023

19. THERAPY DURATION
#1| 40.0 [Day]

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, allergics, pregnancy with last month of period, etc.)
Drug History Sub Section:

#1| Atorvastatin | Atorvastatin | 29-Aug-2023 to 11-Oct-2023 (Historical Drug)
#2| Atorvastatin | Atorvastatin | 19-Jan-2018 to 16-Nov-2022 (Historical Drug)

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-0000048
Immune-mediated myositis is expected according to the reference safety document of Rosuvastatin/Ezetimibe. This adverse reaction was involved in a serious case due to caused/prolonged hospitalization. The intensity of the adverse reaction was unknown. Despite the suspected drug was withdrawn the event was not 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 and the well-known pharmaco-toxicologic profile of the product could enhance the causal relationship. 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 conditional the causal relationship between the drug and the event according to the Karch- Lasagna method.

24b. MFR CONTROL NO.
20-24-ESP-FER-0000048

25b. NAME AND ADDRESS OF REPORTER
Spain
Physician

24c. DATE RECEIVED BY MANUFACTURER
05-Feb-2024

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

DATE OF THIS REPORT
14-May-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1