CIOMS FORM

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	
	Portugal				76 Years	Female	1	Mar	2025	☐ PATIENT DIED

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

#1| Myalgia [Myalgia] |

#2| numbness in the legs [Hypoaesthesia] |

#3| Myopathy [Myopathy] |

This case has been downloaded from the EudraVigilance database without narrative (L2A). (PT-INFARMED-F202508-304).

Patient details: 76 years-old, Female, Elderly. (Height: 155cm; Weight: 48kg)

Medical history: **/...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| Rosuvastatin + Ezetimibe | Rosuvastatin + Ezetimibe | Capsule, hard | Unknown {Lot#: BE0600A}

15. DAILY DOSE(S)
#1| 1CP AFTER DINNER

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

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

17. INDICATION(S) FOR USE
#1| treatment of primary hypercholesterolemia [Primary hypercholesterolaemia]

18. THERAPY DATES (from/to)
#1| 24-Feb-2025 to 12-Jul-2025

19. THERAPY DURATION
#1| 4.0 [Month]

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

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.)
Medical History Sub Section:

#1| Current Condition | Primary hypercholesterolemia [Primary hypercholesterolaemia] | Not Asked to Not Asked (Not Asked)

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: 20-25-PRT-FER-0000469
Myalgia, hypoasthesia and myopathy are expected according to the reference safety document of Rosuvastatin+Ezetimibe. These adverse reactions were involved in a serious case due to disabling/incapacitating reported. The action taken with the drug was withdrawn and the outcome of the events were recovering. In this particular case, the temporal relationship 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. Based on the information provided, the Company assessed as Probable the causal relationship between the drug and the event according to the Karch Lasagna modified method.

24b. MFR CONTROL NO.
20-25-PRT-FER-0000469

25b. NAME AND ADDRESS OF REPORTER
Portugal
Other or unknown Health Care Professional
HCP Other

24c. DATE RECEIVED BY MANUFACTURER
18-Aug-2025

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

DATE OF THIS REPORT
26-Aug-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13 DESCRIBE REACTION(S) continued

- (LLT: Primary hypercholesterolemia)

Suspect: ROSUVASTATINA + EZETIMIBA; Action taken: Drug Withdrawn

Events:

- Myalgia ("mialgia") (LLT: Myalgia); Outcome: Recovering/Resolving
- Numbness in leg ("dermência nas pernas")(LLT: Numbness in leg): Outcome: Recovering/Resolving
- Myopathy ("Miopatia") (LLT: Myopathy); Outcome: Recovering/Resolving

This case has been assessed as Serious