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				72 Years	Male	23	Apr	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| Rhabdomyolysis [Rhabdomyolysis] |

This case has been downloaded from the EudraVigilance database without narrative (L2A). (ES-AEMPS-1736288) as Report from Studies (CMBD_HUPR 2025 , Other studies). This is not a Ferrer study therefore the case has been captured as Spontaneous.

Patient details: 72 years-old, elderly, male
.
Medical history:
- (LLT: Hypercholesteremia)
- Prevention of atherothrombotic events "Prevención de acontecimientos aterotrombóticos" (LLT: Prevention)
- (LLT: Hypertension arterial) **/...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 | Unknown (NOS) | Unknown {Lot#: Unknown}

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

15. DAILY DOSE(S)
#1| 1 cap/24h

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

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

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

18. THERAPY DATES (from/to)
#1| 22-Nov-2024 to 23-Apr-2025

19. THERAPY DURATION
#1| 153.0 [Day]

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#2| Empagliflozin | Empagliflozin | Unknown (NOS) | 1c/24h | Oral | 20-Feb-2025 to 22-Jul-2025
#3| Tresiba | Insulin degludec, Insulin degludec | Unknown (NOS) | 1c/24h | Subcutaneous | 22-Feb-2022 to 22-Jul-2025 **/...continued**

23. OTHER RELEVANT HISTORY (e.g diagnostics, allergics, pregnancy with last month of period, etc.)
Medical History Sub Section:

#1| Current Condition | Hypercholesteremia [Hypercholesterolaemia] |
#2| Current Condition | Prevention of atherothrombotic events [Prophylaxis] |
#3| Current Condition | Hypertension arterial [Hypertension] |
#4| Current Condition | Reduction in the risk of cardiovascular events [Prophylaxis] |
#5| Current Condition | Prevention [Prophylaxis] |**/...continued**

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-ESP-FER-0000456
Rhabdomyolysis 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 action taken with the drug was withdrawn and the outcome of the event was recovered. 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 events according to the Karch Lasagna modified method.

24b. MFR CONTROL NO.
20-25-ESP-FER-0000456

25b. NAME AND ADDRESS OF REPORTER
Spain
Physician
Physician

24c. DATE RECEIVED BY MANUFACTURER
28-Jul-2025

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

DATE OF THIS REPORT
06-Aug-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 20-25-ESP-FER-0000456

ADDITIONAL INFORMATION

7+13 DESCRIBE REACTION(S) continued

- Reduction in the risk of cardiovascular events "Reducción del riesgo de eventos cardiovasculares" (LLT: Prevention)
- (LLT: Prevention)

Suspect: ROSUVASTATINA + EZETIMIBE ; Action taken: Withdrawn

Events:

- Rhabdomyolysis "Rabdomiolisis" (LLT: Rhabdomylosis); Outcome: recovered/resolved

This case has been assessed as Non-Serious

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION continued

#4| Ticagrelor | Ticagrelor | Unknown (NOS) | 1c/12h | Oral | 20-Jan-2025 to 22-Jul-2025
#5| Bisoprolol;Ramipril | Bisoprolol;Ramipril | Unknown (NOS) | 1c/24h | Oral | 20-Jan-2025 to 22-Jul-2025
#6| Omeprazol | Omeprazole, Omeprazole | Unknown (NOS) | 1 c/24h | Oral | 22-Feb-2022 to 22-Jul-2025
#7| Icosapent ethyl | Icosapent ethyl | Unknown (NOS) | 2c/12h | Oral | 20-Jan-2025 to 13-May-2025
#8| Calcifediol | Calcifediol | Unknown (NOS) | 1 CAPSULE / 30 days - ORALLY | Oral | 30-Jun-2023 to 22-Jul-2025
#9| Bilastina Kern Pharma | Bilastine, Bilastine | Unknown (NOS) | 1c/24h | Oral | 30-Jun-2023 to 22-Jul-2025
#10| Acetylsalicylic acid | Acetylsalicylic acid | Unknown (NOS) | 1c/24h | Oral | 20-Jan-2025 to 22-Jul-2025

23. OTHER RELEVANT HISTORY continued

Medical History Sub Section: