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				61 Years	Male	27	Feb	2024	☐ 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| BULTOS EN LA PIEL [Skin mass] |

Other Seriousness Criteria: Medically Significant
#2| Picor [Pruritus] |

This case has been downloaded from the EudraVigilance database without narrative (L2A). (WWID: ES-AEMPS-1518433)

Follow-up (20May2024): A new version of this case was downloaded from the EudraVigilance database on 20May2024. This is an amendment report to add:

/...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#: Unknown}

15. DAILY DOSE(S)
#1| 1 al día

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

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

18. THERAPY DATES (from/to)
#1| 14-Feb-2024 to 05-May-2024

19. THERAPY DURATION
#1| 79.0 [Day]

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

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)
#2| Lorazepam | Lorazepam | Tablet | 1 mg | Unknown | 19-Jan-2024 to Unknown
#3| Apidra | Insulin glulisine | Unknown | 14-Apr-2023 to Unknown

/...continued

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

#1| | Mixed hyperlipidaemia [Type V hyperlipidaemia] | 10-Nov-2010 to
#2| | Morbid obesity [Obesity] | 10-Nov-2010 to
#3| | Insomnia [Insomnia] | 24-Jan-2012 to
#4| | Tobacco abuse [Tobacco abuse] | 27-Feb-2018 to
#5| | Type 2 diabetes mellitus [Type 2 diabetes mellitus] | 10-Nov-2010 to**/...continued**

IV. MANUFACTURER INFORMATION

<table>
<tr><td colspan="2">24a. NAME AND ADDRESS OF MANUFACTURER
FERRER INTERNACIONAL, S.A.
Diagonal Avenue 549, 08029, Barcelona, Spain
Phone: +34936003700,</td><td>26. REMARKS
Company Comments: ID: 20-24-ESP-FER-0000210
Skin mass and Pruritus are expected according to the reference safety information of Rosuvastatin/Ezetimibe. These adverse reactions were involved in a serious case due to other medically important condition. The intensity of the adverse reactions was unknown. The action taken with the suspected drug was unknown and the events were recovering. From a medical point of view, allergic reactions to drugs refer to those ADRs that involve immune mechanisms which can be identified as being a type I through IV immune reaction. Clinical manifestations of allergic reactions range from pruritus and rash to serious reactions such as systemic anaphylaxis and cardiovascular emergencies. In this particular case, the temporal relation 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 possible the causal relationship between the drug and the events according to the Karch Lasagna method.
FU received on 20May2024: Outcome of Itch updated to recovered/resolved and End date of reaction provided. This new information does not change the previous medical assessment (possible)</td></tr>
<tr><td></td><td>24b. MFR CONTROL NO.
20-24-ESP-FER-0000210</td><td rowspan="3">25b. NAME AND ADDRESS OF REPORTER
Spain
HCP Other</td></tr>
<tr><td>24c. DATE RECEIVED BY MANUFACTURER
20-May-2024</td><td>24d. REPORT SOURCE
☐ STUDY ☐ LITERATURE
☒ HEALTH PROFESSIONAL ☐ OTHER:</td></tr>
<tr><td>DATE OF THIS REPORT
14-May-2025</td><td>25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 2</td></tr>
</table>

Mfr. Control Number: 20-24-ESP-FER-0000210

ADDITIONAL INFORMATION

7+13 DESCRIBE REACTION(S) continued

- End date of the ALZIL PLUS 5 MG/10 MG administration.
- Outcome of Itch updated to recoved/resolved and End date of reaction provided (10May2024).
- Time Interval between Beginning of Drug Administration and Start of Reaction / Event of every drug.

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: 116kg, 180cm

ALZIL PLUS 5 MG/10 MG COMPRIMIDOS RECUBIERTOS CON PELICULA, 30 comprimidos, action taken: unknown

LORAZEPAM 1 mg 50 comprimidos, action taken: not changed

TOUJEO 300 UNIDADES/ML DOUBLESTAR SOLUCION INYECTABLE EN PLUMA PRECARGADA, action taken: not changed

APIDRA 100 UNIDADES/ML,SOLOSTAR SOLUCION INYECTABLE EN PLUMA PRECARGADA, action taken: not changed

EBYMECT 5 MG/1.000 MG COMPRIMIDOS RECUBIERTOS CON PELICULA, 56 comprimidos recubiertos con película, action taken: not changed

TRULICITY 1,5 mg SOLUCION INYECTABLE EN PLUMA PRECARGADA, action taken: not changed

Outcome of the reactions: recovering/resolving (skin nodule); recovered/resolved (itch), end date of the reaction Itch: 10May2024; end date reaction skin nodule: asked but unknown

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

#4| Toujeo | Insulin glargine | Solution for injection | Unknown | 09-Jan-2018 to Unknown

#5| Ebymect | Dapagliflozin propanediol monohydrate, Metformin hydrochloride | Film-coated tablet | Unknown | 18-Jul-2017 to Unknown

#6| Trulicity | Dulaglutide | Unknown | 09-Nov-2020 to Unknown

23. OTHER RELEVANT HISTORY continued

Medical History Sub Section: