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				38 Years	Female	4	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| Quemadura química cutánea de primer grado [First degree chemical burn of skin] |

This case has been downloaded from the EudraVigilance database without narrative (L2A)(WWID:ES-AEMPS-1486236).

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

Patient's weight and height: 58kg and 168cm
DERMOFIX 20 MG/G GEL, 1 tubo de 100 g, action taken: withdrawn
Outcome of the reaction: recovering/resolving; end date reaction: asked but unknown

☐ 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| DERMOFIX | Sertaconazole | Gel | 2 % {Lot#: Unknown}

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

15. DAILY DOSE(S)
#1| untar la crema por la mañana y la noche

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

17. INDICATION(S) FOR USE
#1| Pityriasis versicolor [Tinea versicolour]

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

18. THERAPY DATES (from/to)
#1| 01-Feb-2024 to 04-Feb-2024

19. THERAPY DURATION
#1| 4.0 [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.)

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-0000067
First degree chemical burn is unexpected according to the reference safety document of Sertaconazole. This adverse reaction was involved in a serious case due to other medically important condition. The suspected drug was withdrawn and the event was recovered. Side effects with sertaconazole therapy may include contact dermatitis, burning on application site and skin dryness. The active ingredient sertaconazole nitrate is only absorbed in very small quantities into the blood circulation and systemic side effects are not expected. In this particular case, the temporal association and the positive withdrawn 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 considered 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-0000067

25b. NAME AND ADDRESS OF REPORTER
Spain
Consumer

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

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

DATE OF THIS REPORT
14-May-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1