

SUSPECT ADVERSE REACTION REPORT										

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY France	2. DATE OF BIRTH			2a. AGE 47 Years	3. SEX Female	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year			Day	Month	Year	
							1	Dec	2024	
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 prurit vulvaire [Vulvovaginal pruritus] Other Seriousness Criteria: Medically Significant #2 Application site reaction [Application site reaction] This case has been downloaded from the EudraVigilance database without narrative (L2A). (WWID: FR-AFSSAPS-PP2024001458) 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: 63kg, 164cm. /...continued										<input type="checkbox"/> PATIENT DIED <input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION <input type="checkbox"/> INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY <input type="checkbox"/> LIFE THREATENING <input type="checkbox"/> CONGENITAL ANOMALY <input checked="" type="checkbox"/> OTHER

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1 MONAZOL Sertaconazole Cream 2 % {Lot#: V009}		20 DID REACTION ABATE AFTER STOPPING DRUG? #1 <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
15. DAILY DOSE(S) #1 Matin et soir	16. ROUTE(S) OF ADMINISTRATION #1 Cutaneous	
17. INDICATION(S) FOR USE #1 Demengeaison, diagnostic vaginose candida albicans [Candida infection]		21. DID REACTION REAPPEAR AFTER REINTRODUCTION? #1 <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
18. THERAPY DATES (from/to) #1 26-Nov-2024 to 06-Dec-2024	19. THERAPY DURATION #1 9.0 [Day]	

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction) #2 Orofluco Fluconazole DOSE INCONNUE Oral 26-Nov-2024 to Unknown
23. OTHER RELEVANT HISTORY (e.g diagnostics, allergics, pregnancy with last month of period, etc.) Medical History Sub Section: #1 Other Penicillin allergy [Drug hypersensitivity]

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-FRA-FER-0000011 Application site reaction and Vulvovaginal pruritus are expected according to the reference safety document of Sertaconazole. These adverse reactions were involved in a serious case due to other medically important condition. The intensity of the adverse reactions was unknown. The suspected drug was withdrawn and the event were not 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 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 etiologies. In summary, based on the information provided, the Company considered as conditional the causal relationship between the drug and the events according to the Karch Lasagna method
	24b. MFR CONTROL NO. 20-25-FRA-FER-0000011	25b. NAME AND ADDRESS OF REPORTER France Consumer
24c. DATE RECEIVED BY MANUFACTURER 14-Jan-2025	24d. REPORT SOURCE	

	<input type="checkbox"/> STUDY <input type="checkbox"/> HEALTH PROFESSIONAL	<input type="checkbox"/> LITERATURE <input checked="" type="checkbox"/> OTHER: Consumer (including Attorneys)	
DATE OF THIS REPORT 14-May-2025	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> FOLLOWUP: 1		

ADDITIONAL INFORMATION**7+13 DESCRIBE REACTION(S) continued**

Patient's comments: No allergies, I don't take any other medications, alcohol, or cigarettes of any kind. I was allergic to penicillin when I was very young. I don't know now; I haven't had any tests (Pas d'allergie particulière, je ne consomme ni autre médicaments ni alcool ni cigarettes de tous genres Très jeune j'étais allergique à la pénicilline, je ne sais pas maintenant, je n'ai pas refais de tests)

MONAZOL 2 POUR CENT, crème, action taken: withdrawn

OROFLUCO 150 mg, gélule, action taken: reported in blank; indication: Candida albicans infection

Outcome: not recovered/not resolved/ongoing; end date of the reactions: not asked