Mfr. Control Number : 202501330
Worldwide Number : CR-KERNPHARMA-202501330

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. INITIALS	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	
[Privacy]	CR				24 Years	F	uu	Apr	2025	

7+13 DESCRIBE REACTION(S) (including relevant tests/lab data) Event Verbatim [Low Level Term]

#1 Device breakage [Device breakage] (10012575 v28.0) / Outcome : recovered / Start date : uu-Apr-2025 / End date : 30-Apr-2025

#2 Vulvovaginal discomfort [Vulvovaginal discomfort] (10047786 v28.0) / Outcome : recovered / Start date : 29-Apr-2025 / End date : 30-Apr-2025

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☐ HOSPITALIZATION
- ☐ DISABILITY OR INCAPACITY
- ☐ CONGENITAL ANOMALY/BIRTH DEFECT
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUGS(S) (include generic name)

#1 FemeGyn Ring® 0.120mg /0.015mg each 24 hours vaginal release (Etonogestrel; Ethinylestradiol); Batch/Lot number : V021

20. DID REACTION ABATE AFTER STOPPING DRUG?
■ YES ☐ NO ☐ NA

15. DAILY DOSE(S) (dose per interval/unit/separate dose/text)
Unknown

16. ROUTE(S) OF ADMINISTRATION
#1 Vaginal use

17. INDICATION(S) FOR USE
#1 Hormonal contraception

21. DID REACTION REAPPEAR AFTER REINTRODUCTION ?
☐ YES ■ NO ☐ NA

18. THERAPY DATES (from/to)
#1 uu-May-2024 /

19. THERAPY DURATION
#1 1 Year

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUGS(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.)

From / To Dates — Description
#1 / / Continuing : /

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
Kern Pharma
Pol. Ind. Colon II, C/Venus, 72
08228 Terrassa, Barcelona ES

26. REMARKS

24b. MFR CONTROL NO.
CR-KERNPHARMA-202501330

25b. NAME AND ADDRESS OF REPORTER
#1 Costa Rica

24c. DATE RECEIVED BY MANUFACTURER
05-May-2025

24d. REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
■ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
07-May-2025

25a. REPORT TYPE
■ INITIAL ☐ FOLLOW UP :

14-19. SUSPECTS DRUGS (full)

Seq. No.	:	1
Drug	:	FemeGyn Ring® 0.120mg /0.015mg each 24 hours vaginal release (Etonogestrel; Ethinylestradiol)
Daily dose	:	Unknown
Dosage text	:	
Route of administration	:	Vaginal use
Batch / Lot number	:	V021
Indication for use	:	Hormonal contraception (10073728 v28.0)
Therapy dates (start/end)	:	uu-May-2024 /
Therapy duration	:	1 Year
Did reaction abate ?	:	Yes
Did reaction reappear ?	:	Yes-No (rechallenge was done, reaction did not recur)

CASE DESCRIPTION (Case narrative)

Non serious case received from partner Menarini with day 0 = 05May2025 and reference CA-02042025. Case regarding a Femegyn ring that broke and caused vulvovaginal discomfort.

Start date: April-2025 / End date: 30-April-2025
2) Vulvovaginal discomfort (10047786)
Start date: 29-April-2025 / End date: 30-April-2025 (After dechallenge).

Patient presents at the pharmacy and indicates that since the night of April 29, she presented vaginal discomfort that she describes as a "sting", patient indicate that it was more intense over time. On April 30, the discomfort was greater and she decided to remove the ring (she had placed the ring since April 23), which had a break in the union part and therefore she did not replace it.

At the pharmacy they told her that she had to insert a new device and that if more than 3 hours had passed since removing the previous one, she had to use an additional barrier method for seven days.

The patient places a new device and reports no discomfort again, the patient has recovered from the reported discomfort.

Note: Patient is using Femegyn Ring since May 2024.

Case related to product defect – PD code: LF CC940 || Batch: V021 / Expiration date: 09/2025on-serious by the reporter.

The company has assessed Device breakage and Vulvovaginal discomfort as probably related to Etonogestrel + Ethinylestradiol therapy using the Karch Lasagna algorithm (modified).

DUPLICATE NUMBERS

#1 CA-04052025 (MENARINI)