Mfr. Control Number : 202501570
Worldwide Number : CR-KERNPHARMA-202501570

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				33 Years	M	15	May	2023	

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

#1 Hand rash [Hand rash] (10019117 v28.0) / Outcome : recovered / Start date : 15-May-2023 / End date : 19-May-2023

#2 flushed skin [Flushed skin] (10016824 v28.0) / Outcome : recovered / Start date : 15-May-2023 / End date : 19-May-2023

- ☐ 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 Mencetamol® 1 g /10 mL oral solution (PARACETAMOL); Batch/Lot number : [UNK]

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

15. DAILY DOSE(S) (dose per interval/unit/separate dose/text)
#1 1 gram 1 time(s) every Total

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

17. INDICATION(S) FOR USE
#1 Acute pain

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

18. THERAPY DATES (from/to)
#1 15-May-2023 / 15-May-2023

19. THERAPY DURATION
#1

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-202501570

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

24c. DATE RECEIVED BY MANUFACTURER
02-Jun-2025

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

DATE OF THIS REPORT
05-Jun-2025

25a. REPORT TYPE
■ INITIAL ☐ FOLLOW UP :

14-19. SUSPECTS DRUGS (full)

Seq. No.	:	1
Drug	:	Mencetamol® 1 g /10 mL oral solution (PARACETAMOL)
Daily dose	:	1 gram 1 time(s) every Total
Dosage text	:	
Route of administration	:	Oral use
Batch / Lot number	:	[UNK]
Indication for use	:	Acute pain (10066714 v28.0)
Therapy dates (start/end)	:	15-May-2023 / 15-May-2023
Therapy duration	:	
Did reaction abate ?	:	Yes
Did reaction reappear ?	:	No–NA (no rechallenge was done, recurrence is not applicable)

CASE DESCRIPTION (Case narrative)

Case received from partner Menarini regarding Mencetamol. Day 0 = 02Jun2025, non-serious reaction.

1) Hand rash (10019117)
2) Flushed skin (10016824)
Start date: 15-May-2023 / End date: 19-May-2025

Patient reports he was given 1 g of mencetamol, and after taking it, a flushing and a rash appeared on his hands 20- 30 minutes later. The patient discontinued the product, and the rash continued for up to 4 days, then diminished and disappeared.

The patient is now fully recovered.

Weight: 95 Kg / Height: 170 cm

The company has assessed Hand rash and Flushed skin as probably related to Mencetamol therapy using the Karch Lasagna algorithm (modified).

DUPLICATE NUMBERS

#1 CA-01062025 (MENARINI)