Mfr. Control Number : 202502314
Worldwide Number : GT-KERNPHARMA-202502314

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]	GT				10 Years	M	20	Aug	2025	

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

#1 Disminución de temperatura entre 35° y 34°, hipotermia [Hypothermia] (10021113 v28.0) / Outcome : recovered / Start date : 20-Aug-2025 / End date : 20-Aug-2025

#2 labios morados [Blue lips] (10005881 v28.0) / Outcome : recovered / Start date : 20-Aug-2025 / End date : 20-Aug-2025

#3 frío [Feeling cold] (10016326 v28.0) / Outcome : recovered / Start date : 20-Aug-2025 / End date : 20-Aug-2025

#4 Blanco (tono en piel) [Pale] (10033532 v28.0) / Outcome : recovered / Start date : 20-Aug-2025 / End date : 20-Aug-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 AGEFEN KIDS 200 mg suspensión oral (ibuprofen); Batch/Lot number : X006

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

15. DAILY DOSE(S) (dose per interval/unit/separate dose/text)
#1 200 milligram 1 time(s) every Total

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

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

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

18. THERAPY DATES (from/to)
#1 20-Aug-2025 / 20-Aug-2025

19. THERAPY DURATION
#1 1 Day

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUGS(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1 Enantyum gel () ; / ; ; ; ; Unknown

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.
GT-KERNPHARMA-202502314

25b. NAME AND ADDRESS OF REPORTER
#1 Guatemala

24c. DATE RECEIVED BY MANUFACTURER
21-Aug-2025

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

DATE OF THIS REPORT
25-Aug-2025

25a. REPORT TYPE
■ INITIAL ☐ FOLLOW UP :

14-19. SUSPECTS DRUGS (full)

Seq. No.	:	1
Drug	:	AGEFEN KIDS 200 mg suspensión oral (ibuprofen)
Daily dose	:	200 milligram 1 time(s) every Total
Dosage text	:	
Route of administration	:	Oral use
Batch / Lot number	:	X006
Indication for use	:	Foot pain (10016974 v28.0)
Therapy dates (start/end)	:	20-Aug-2025 / 20-Aug-2025
Therapy duration	:	1 Day
Did reaction abate ?	:	Yes
Did reaction reappear ?	:	No–NA (no rechallenge was done, recurrence is not applicable)

22. CONCOMITANT DRUGS (full)

Seq. No.	:	1
Drug	:	Enantyum gel ()
Daily dose	:	Unknown
Dosage text	:	
Route of administration	:	
Indication for use	:	
Therapy dates (start/end)	:	/
Therapy duration	:	

CASE DESCRIPTION (Case narrative)

This initial serious spontaneous report with reference number GT-KERNPHARMA-202502314 was received on 21-Aug-2025 by partner AGEFINSA with internal reference R-2025-01. Case reported by a consumer regarding AGEFEN KIDS 200 mg suspensión oral (ibuprofen) (batch number is X006).

The mother of a 10-year-old male patient reported that on 20 August 2025 her son was taken to a traumatologist because he suffered from sole of the foot pain. He was prescribed AGEFEN KIDS (ibuprofen) 200 mg oral suspension every 8h orally for 5 days and Enantyum gel topical every 12h for 5 days. The patient was administered AGEFEN KIDS 200 mg on 20 August 2025 at night (9-10 PM) and almost immediately he experienced body temperature decreased to 35-34ºC (hypothermia), blue lips (cyanosis), feeling cold and he was pale (pallor). AGEFEN KIDS was withdrawn and the adverse reactions resolved. Next day on 21 August 2025 the patient went to school without any issue. The patient's mother tried to contact the doctor but unsuccessfully.

The company has assessed hypothermia, cyanosis, feeling cold and pallor as conditionally related to ibuprofen therapy using the Karch Lasagna algorithm (modified).

Further information is not available.