SUSPECT ADVERSE REACTION REPORT

CR-MEN-114520(0)

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	4-6 REACTION ONSET		
		Day	Month	Year	Years		Day	Month	Year
Masked	COSTA RICA				36	Male	10	Feb	2025

7+13 DESCRIBE REACTION(S) (including relevant tests/lab data)

1) Hand rash (Hand rash (10019117), Rash (10037844))
(10/Feb/2025 - 14/Feb/2025) - Recovered/Resolved
2) Flushed skin (Flushed skin (10016824), Flushing (10016825))
(10/Feb/2025 - 14/Feb/2025) - Recovered/Resolved

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENCE OR SIGNIFICANT DISABILITY/INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II. SUSPECT DRUG(S)INFORMATION

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

1) enantyum (Dexketoprofen trometamol, Dexketoprofen trometamol) (Suspect) (Granules for oral solution)(Unknown)

Cont..

20. DID EVENT ABATE AFTER STOPPING DRUG? ☑ YES ☐ NO ☐ NA

15. DAILY DOSE(S)

1) (25 milligram(s), 1 in 1 Total)

16. ROUTE(S) OF ADMINISTRATION

1) Oral

21. DID EVENT REAPPEAR AFTER REINTRODUCTION ☐ YES ☐ NO ☑ NA

(NA : Not Applicable)

17. INDICATION(S) FOR USE

1) Headache [10019211 - Headache]

18. THERAPY DATE(S) (from/to)	19. THERAPY DURATION
1) (10/Feb/2025 - 10/Feb/2025)	1) 1 Days

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

No concomitants used/reported

23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

1) FLUSHED SKIN (10016824, Flushed skin) (//2023 -) (Continuing: No)

Cont..

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER

Name : A. Menarini Industrie Farmaceutiche Riunite S.r.l.
Via Sette Santi, 3
Florence, 50131, ITALY

24.REPORT NULLIFIED	24b. MFR CONTROL NO.
☐ YES ☐ NO	CR-MEN-114520(0)
24c. DATE RECEIVED BY MANUFACTURER: 02/Jun/2025	24d. REPORT SOURCE: ☐ STUDY ☐ LITERATURE ☑ HEALTH PROFESSIONAL
DATE OF THIS REPORT: 12/Jun/2025	25a. REPORT TYPE: ☑ INITIAL ☐ FOLLOWUP

= Continuation attached sheet(s)..

Continuation Sheet for CIOMS report

7+13 DESCRIBE REACTION(S) (including relevant tests/lab data) (Continuation...)

Event Description :

This non-serious spontaneous case was received from a dentist reported through direct contact to sales force in Costa Rica on 02-Jun-2025.
It involved a 36-year-old male patient (weight: 95 kgs and height: 170 cms) who experienced hand rash and flushed skin (a rash and flushed skin appeared on the hands) since 10-Feb-2025 within 20-30 minutes after administration of Enantyum.
Lab data was not reported.
The patient was treated with prescribed Enantyum (Dexketoprofen trometamol) 25 mg granules for oral solution orally 1 in 1 total for headache on 10-Feb-2025.
Concomitant drugs information was not provided.
Enantyum was withdrawn on the same day (the patient decided to stop taking the product).
Outcome of the reported events was resolved on 14-Feb-2025 (the reported symptoms disappeared after 3-4 days and the patient was fully recovered to date).
Medical history included flushed skin and hand rash on an unspecified date in 2023, experienced due to the past drug therapy Mencetamol (Paracetamol) 1 g (unknown frequency, formulation and route of administration) for pain (not specified pain) in 2023.
No additional information was provided.

Company Remarks (Sender's Comments) :

Based on the received information the causal relationship between the reported events and suspect drug was assessed as possible due to positive temporal association, positive dechallenge and known pharmacological profile of the drug. The case lacks information on other concomitant medications if any.
The case was reported as non-serious.

14.SUSPECT DRUG(S) (Continuation...)

Product-Reaction Level

1) Drug	:	enantyum (Dexketoprofen trometamol)
Active Substance	:	Dexketoprofen trometamol
Drug Characterization	:	Suspect
Form of Admin	:	Granules for oral solution
Lot Number	:	Unknown
Daily Dose	:	(25 milligram(s), 1 in 1 Total)
Route of Admin	:	Oral
Indications	:	Headache [10019211 - Headache]
Therapy Dates	:	From : 10/Feb/2025 To :10/Feb/2025
Therapy Duration	:	1 Days
Action(s) Taken With Drug	:	Drug withdrawn

Causality

1) Hand rash (Hand rash - 10019117, Rash - 10037844)		
Causality as per reporter	:	Possible
Causality as per Mfr	:	Possible
DeChallenge	:	Positive
ReChallenge	:	Not Applicable
2) Flushed skin (Flushed skin - 10016824, Flushing - 10016825)		
Causality as per reporter	:	Possible
Causality as per Mfr	:	Possible
DeChallenge	:	Positive
ReChallenge	:	Not Applicable

Labeling :

1) Hand rash	
CORE	Labeled
2) Flushed skin	
CORE	Labeled

23. OTHER RELEVANT HISTORY (Continuation...)

2) HAND RASH (10019117 , Hand rash) (//2023 -) (Continuing : NO)

Past Therapy (ies)

Product Name	:	MENCETAMOL
Indication	:	Pain (10033371)

Continuation Sheet for CIOMS report

Start Date : //2023
Stop Date :

Primary Reporter:
Other health professional
COSTA RICA