Mfr. Control Number : 202500040
Worldwide Number : CR-Noucor-202500040

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	
	CR				1 Year	M	08	Jul	2025	

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

#1 / Rupax was prescribed for a 1-year-old child; the label approves it for children 2 and older. [Off label use] (10053762 v28.0) / Outcome : unknown / Start date : 08-Jul-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 Rupax Oral Solution (Rupatadine fumarate | 1 | milligram per millilitre); 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 2.5 millilitre

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

17. INDICATION(S) FOR USE
#1

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

18. THERAPY DATES (from/to)
#1 08-Jul-2025 /

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
Noucor Health

ES

26. REMARKS

24b. MFR CONTROL NO.
CR-Noucor-202500040

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

24c. DATE RECEIVED BY MANUFACTURER
08-Jul-2025

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

DATE OF THIS REPORT
17-Jul-2025

25a. REPORT TYPE
■ INITIAL ☐FOLLOW UP :

14-19. SUSPECTS DRUGS (full)

Seq. No.	:	1
Drug	:	Rupax Oral Solution (Rupatadine fumarate | 1 | milligram per millilitre)
Daily dose	:	2.5 millilitre
Dosage text	:	
Route of administration	:	Oral use
Batch / Lot number	:	[UNK]
Indication for use	:	
Therapy dates (start/end)	:	08-Jul-2025 /
Therapy duration	:	
Did reaction abate ?	:	
Did reaction reappear ?	:	

CASE DESCRIPTION (Case narrative)

This spontaneous non-serious case (202500040) was received on 08-Jul-2025 by the MAH of rupatadine in Costa Rica (Menarini Latin Farma code: CA-06072025) originally reported by a physician, via phone.

This case concerns a 1-year-old male patient from Costa Rica, weight < 10 Kg.

Rupax was prescribed for a 1-year-old child; the label approves it for children 2 and older. The patient did not experience any adverse effects or associated problems. The physician states that follow-up contact is not permitted, so the patient's progress cannot be determined

Outcome of the case: Unknown

Reporter's comment:
Causality as per Reporter: Possible

Company comment (Noucor):
The expectedness of the special situation Off label use is Not applicable.
The company causality assessment for the special situation Off label use is Not assessable.