

SUSPECT ADVERSE REACTION REPORT	
2025OHG022564	

## I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE Years	3. SEX	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
Masked	GUATEMALA	Day	Month	Year		Unknow	Day	Month	Year	
7+13 DESCRIBE REACTION(S) (including relevant tests/lab data)										<input type="checkbox"/> PATIENT DIED <input type="checkbox"/> LIFE THREATENING <input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION <input type="checkbox"/> RESULTS IN PERSISTENCE OR SIGNIFICANT DISABILITY/INCAPACITY <input type="checkbox"/> CONGENITAL ANOMALY <input type="checkbox"/> OTHER MEDICALLY IMPORTANT CONDITION
MedDRA Version : v.28.0										
1) allegra doesn't work for me (Lack of drug effect (10023610), Drug ineffective (10013709)) (Asked but Unknown - ) - Unknown										
2) no adverse event (No adverse event (10067482), No adverse event (10067482)) (Asked but Unknown - ) - Unknown										

## II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)		20. DID EVENT ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA  21. DID EVENT REAPPEAR AFTER REINTRODUCTION <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA (NA : Not Applicable)
1) Allegra (FEXOFENADINE HYDROCHLORIDE, FEXOFENADINE HYDROCHLORIDE) (Suspect) (Unknown)(Unknown) Cont..		
15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION	
	1) Unknown	
17. INDICATION(S) FOR USE		
1) Drug use for unknown indication [10057097 - Drug use for unknown indication] Asked but Unknown		
18. THERAPY DATE(S) (from/to)	19. THERAPY DURATION	
(Asked but Unknown - )		

## 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.)
MedDRA Version : v.28.0

## IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER		
Name : CU_LATAM for the Sanofi group of companies, 82 avenue Raspail CHILE		
24. REPORT NULLIFIED	24b. MFR CONTROL NO.	
<input type="checkbox"/> YES <input type="checkbox"/> NO	2025OHG022564	
24c. DATE RECEIVED BY MANUFACTURER	24d. REPORT SOURCE	
19/Jul/2025	<input type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL	
DATE OF THIS REPORT	25a. REPORT TYPE	
01/Aug/2025	<input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP	

= Continuation attached sheet(s)..

## Continuation Sheet for CIOMS report

## 3. SEX

Unknown

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

## Event Description :

This non-serious, valid, spontaneous case from Guatemala was received on 19-Jul-2025 from a patient via social media (Facebook).

It concerns patient of unknown age and gender who was being treated with fexofenadine hydrochloride (Allegra) which doesn't work for the patient, with no adverse event.

No family history, medical history, concurrent condition, past medications or concomitant medications were reported.

On an unknown date, the patient started therapy with fexofenadine hydrochloride at an unknown dose, route, form, strength, frequency, batch number and expiry date.

The reporter stated that personally, that medication called ALLEGRA doesn't work for him/her (PT: Drug ineffective) (Onset date and Latency: Unknown), with no adverse event, which was considered non-serious. But he/she loved her/him furry friend, and he/she don't mind shaking and picking up the hairs she leaves everywhere!

No relevant lab data was reported.

Action taken was not applicable

Outcome was unknown

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

## Product-Reaction Level

1) Drug	: Allegra (FEXOFENADINE HYDROCHLORIDE)
Active Substance	: FEXOFENADINE HYDROCHLORIDE
Drug Characterization	: Suspect
Form of Admin	: Unknown
Lot Number	: Unknown
Route of Admin	: Unknown
Indications	: Drug use for unknown indication Asked but Unknown [10057097 - Drug use for unknown indication]
Therapy Dates	: From : Asked but Unknown
Action(s) Taken With Drug	: Not applicable

## Causality

1) allegra doesn't work for me (Lack of drug effect - 10023610, Drug ineffective - 10013709 )

Causality as per reporter	: Related
Causality as per Mfr	: Related
DeChallenge	: Not applicable
ReChallenge	: Not Applicable

2) no adverse event (No adverse event - 10067482, No adverse event - 10067482 )

Causality as per reporter	: Related
Causality as per Mfr	: Related
DeChallenge	: Not applicable
ReChallenge	: Not Applicable

## Labeling :

1) allegra doesn't work for me

CORE	Labeled
IB	Labeled

2) no adverse event

CORE	Labeled
IB	Labeled

Primary Reporter:

Name:Masked Masked

Patient

Continuation Sheet for CIOMS report

GUATEMALA