

<b>SUSPECT ADVERSE REACTION REPORT</b>  2025OHG023303												

## I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) Masked	1a. COUNTRY GUATEMALA	2. DATE OF BIRTH			2a. AGE Years	3. SEX Unknow Cont..	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year			Day	Month	Year	
7+13 DESCRIBE REACTION(S) (including relevant tests/lab data) MedDRA Version : v.28.0 1) i feel like it's making me very sleepy (Sleepy (10041018), Somnolence (10041349)) (Asked but Unknown - ) - Unknown 2) the user also wants to know if the medicine is genuine or counterfeit (Suspected counterfeit product (10071287), Suspected counterfeit product (10071287)) (Asked but Unknown - ) - Unknown									<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	

## II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S)(include generic name) 1) pharmaton vitality (PHARMATON-PANAX GINSENG EXTRACT (G 115) + VITAMINS + MINERALS, TOCOPHERYL ACETATE) (Suspect) (S0048801)		20. DID EVENT ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
15. DAILY DOSE(S)  16. ROUTE(S) OF ADMINISTRATION 1) Unknown		
17. INDICATION(S) FOR USE [10057097 - Drug use for unknown indication] Asked but Unknown		21. DID EVENT REAPPEAR AFTER REINTRODUCTION <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA (NA : Not Applicable)
18. THERAPY DATE(S) (from/to) (Asked but Unknown - )	19. THERAPY DURATION	

## 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 <input type="checkbox"/> YES <input type="checkbox"/> NO	24b. MFR CONTROL NO. 2025OHG023303	
24c. DATE RECEIVED BY MANUFACTURER 28/Jul/2025	24d. REPORT SOURCE <input type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL	
DATE OF THIS REPORT 07/Aug/2025	25a. REPORT TYPE <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 28-Jul-2025 from a patient via affiliate.

It concerns patient of unknown age, age group and gender who reported that patient feel like it was making him/her very sleepy and the user also wanted to know if the medicine was genuine or counterfeit, while being treated with pharmaton-panax ginseng extract (g 115) + vitamins + minerals (Pharmaton vitality)

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

On an unknown date, the patient started pharmaton-panax ginseng extract (g 115) + vitamins + minerals with unknown dose, route, frequency, formulation, strength, and indication of use. lot/batch number: S0048801, expiration date: Jan-2026

Reportedly, patient bought pharmaton vitality but patient feel like it was making him/her very sleepy (Somnolence). The user also wanted to know if the medicine was genuine or counterfeit (Suspected counterfeit product) (onset date and latency: unknown) which was considered non-serious.

No relevant lab data was reported.

Action taken with the suspect was not applicable for the event suspected counterfeit product and unknown for the event somnolence.

Corrective treatment: not reported for the event somnolence.

Outcome was unknown.

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

## Product-Reaction Level

1) Drug	: pharmaton vitality (PHARMATON-PANAX GINSENG EXTRACT (G 115) + VITAMINS + MINERALS)
Active Substance	: 1) TOCOPHERYL ACETATE
	2) THIAMINE NITRATE
	3) ZINC SULPHATE MONOHYDRATE
	4) SODIUM SELENITE
	5) RIBOFLAVIN
	6) PYRIDOXINE HYDROCHLORIDE
	7) PANAX GINSENG EXTRACT (G 115)
	8) NICOTINAMIDE
	9) MANGANESE SULPHATE MONOHYDRATE
	10) MAGNESIUM OXIDE
	11) FOLIC ACID
	12) FERROUS SULFATE
	13) CYANOCOBALAMIN
	14) COPPER SULPHATE, ANHYDROUS
	15) CHOLECALCIFEROL CONCENTRATE (POWDER FORM)...
	16) CALCIUM HYDROGEN PHOSPHATE (ANHYDROUS)
	17) BIOTIN
	18) BETACAROTENE
	19) ASCORBIC ACID
Drug Characterization	: Suspect
Form of Admin	: Unknown
Lot Number	: S0048801
Route of Admin	: Unknown
Indications	: Asked but Unknown [10057097 - Drug use for unknown indication]
Therapy Dates	: From : Asked but Unknown
Action(s) Taken With Drug	: Not applicable

## Causality

1) i feel like it's making me very sleepy (Sleepy - 10041018, Somnolence - 10041349 )

## Continuation Sheet for CIOMS report

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

2) the user also wants to know if the medicine is genuine or counterfeit (Suspected counterfeit product - 10071287, Suspected counterfeit product - 10071287 )

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

## Labeling :

1) i feel like it's making me very sleepy

CORE	UnLabeled
IB	UnLabeled

2) the user also wants to know if the medicine is genuine or counterfeit

CORE	Labeled
IB	Labeled

## Primary Reporter:

Name:Masked Masked

Patient

GUATEMALA

Email:

Masked