SUSPECT ADVERSE REACTION REPORT

2024A-1388646

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE Years	3. SEX	4-6 REACTION ONSET		
		Day	Month	Year			Day	Month	Year
Masked	GUATEMALA	UNK	UNK	UNK	5	Female	UNK	UNK	UNK

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

1) Cough (Cough (10011224), Cough (10011224))
Recovering/Resolving

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) DAYAMINERAL JARABE - 240 ML (6992) (AACH>ASCORBIC ACID-VC/CALCIUM/CHOLECALCIFEROL-VD3/ CHOLINE/CYANOCOBALAMIN-VB12/CYSTEINE/DEXPANTHENOL/INOSITOL/IODINE/IRON/MAGNESIUM/ MANGANESE/NICOTINAMIDE/PHOSPHO

Continued

15. DAILY DOSE(S)

1) (1 in 1 Day)

16. ROUTE(S) OF ADMINISTRATION

1) Oral

17. INDICATION(S) FOR USE

1) Unknown indication [10057097 - Drug use for unknown indication]

18. THERAPY DATE(S) (from/to)

UNK

19. THERAPY DURATION

UNK

20. DID EVENT ABATE AFTER STOPPING DRUG?

☐ YES ☐ NO ☑ NA

21. DID EVENT REAPPEAR AFTER REINTRODUCTION

☐ YES ☐ NO ☑ NA

(NA : Not Applicable)

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.)

UNK

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER

Name : ABBOTT GPV
Thomas Nisslein,
Freundallee 9A, Hannover, 30173, GERMANY
pv.qppv@abbott.comand49-3514-5116750

24.REPORT NULLIFIED

☐ YES ☐ NO

24b. MFR CONTROL NO.

2024A-1388646

24c. DATE RECEIVED BY MANUFACTURER

10-Apr-2025

24d. REPORT SOURCE

☐ STUDY ☐ LITERATURE ☑ HEALTH PROFESSIONAL

DATE OF THIS REPORT

14-Apr-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 :

On 24-Sep-2024 a spontaneous valid report was received from a Physician in GUATEMALA concerning a 5 Year(s) old Female patient, who experienced Cough under treatment with DAYAMINERAL JARABE - 240 ML (6992), Syrup Pediatric, Oral, (1 every 1 Day). Indication for use was unknown.

The patient initiated treatment on DAYAMINERAL JARABE - 240 ML (6992) on an unknown date.

For DAYAMINERAL JARABE - 240 ML (6992) the lot number was reported as UNKNOWN.

On an unknown date the patient experienced Cough. The event was considered non serious.

The event Cough is recovering.

The status of the DAYAMINERAL JARABE - 240 ML (6992) medication is unknown.

Concomitant medications were not reported.
There were no concomitant diseases reported.
There was no past medical history reported.

Causality assessment for DAYAMINERAL JARABE - 240 ML (6992)
Reporter causality for the event Cough: Not Reported

Following information was reported:
The patient is given a spoonful of Dayamineral and a few days later she starts to cough. The patient suffers from coughing every time she takes Dayamineral.

After clarification with Abbott's sales representative changed from E2B form: "Dose: 1 Frequency unit: Day" to "Dosage text: 1 teaspoon per day, Frequency unit: Day: Frequency: 1".

According to the local monograph:
Cough: unexpected

Follow up information was received 10-Apr-2025:
Contact attempt information was received.

Three follow-up attempts were made unsuccessful on the following dates:

1. 27-Dec-24
2. 17-Feb-25
3. 20-Mar-25

There is no other safety information.

Pharmacovigilance Comments :

Additional Report Source:
Spontaneous,Spontaneous

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

Product-Reaction Level

1) Drug : DAYAMINERAL JARABE - 240 ML (6992) (AACH>ASCORBIC ACID-VC/CALCIUM/CHOLECALCIFEROL-VD3/CHOLINE/CYANOCOBALAMIN-VB12/CYSTEINE/DEXPANTHENOL/INOSITOL/IODINE/IRON/MAGNESIUM/

Continuation Sheet for CIOMS report

MANGANESE/NICOTINAMIDE/PHOSPHORUS/PYRIDOXINE-VB6/RETINOL-VA/RIBOFLAVIN-VB2/ THIAMINE-VB1/ZINC)

Active Substance : 1) DEXPANTHENOL
2) CYANOCOBALAMIN (VITAMIN B12)
3) PYRIDOXINE (VITAMIN B6)
4) RIBOFLAVIN (VITAMIN B2)
5) THIAMINE (VITAMIN B1)
6) ASCORBIC ACID (VITAMIN C)
7) CHOLECALCIFEROL (VITAMIN D3)
8) CHOLINE
9) INOSITOL
10) RETINOL (VITAMIN A)
11) NICOTINAMIDE
12) CYSTEINE
13) PHOSPHORUS
14) MANGANESE
15) IRON
16) CALCIUM
17) MAGNESIUM
18) ZINC
19) IODINE

Drug Characterization : Suspect
Form of Admin : Syrup Pediatric
Lot Number : UNKNOWN
Daily Dose : (1 in 1 Day)
Route of Admin : Oral
Indications : Unknown indication [10057097 - Drug use for unknown indication]
Action(s) Taken With Drug : Unknown

Causality

1) Cough (Cough - 10011224, Cough - 10011224)
Causality as per reporter : Not Reported
DeChallenge : Not applicable
ReChallenge : Not Applicable

15. DAILY DOSE(S) (Continuation...)

Dosage Text :

Drug 1 :AACH>ASCORBIC ACID-VC/CALCIUM/CHOLECALCIFEROL-VD3/CHOLINE/CYANOCOBALAMIN-VB12/CYSTEINE/DEXPANTHENOL/ INOSITOL/IODINE/IRON/MAGNESIUM/MANGANESE/NIC OTINAMIDE/PHOSPHORUS/PYRIDOXINE-VB6/RETINOL-VA/RIBOFLAVIN-VB2/ THIAMINE-VB1/ZINC

1) 1 teaspoon per day