SUSPECT ADVERSE REACTION REPORT

BH-2025-016303

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	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	Years		Day	Month	Year	
UNKNOWN	DOMINICAN Cont..	??/??/??	??/??/??	??/??/??	Unkn	Male	??/??/??	??/??/??	??/??/??	

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

MedDRA Version : v.28.0

1) STRONG UNDERARMP ODOR (Body odour (10005902), Skin odour abnormal (10040904))
Recovered/Resolved

- ☐ 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) CARDISPAN (LEVOCARNITINE) (Suspect) (Solution)(401761)

Cont..

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
Unkn	1) Oral

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

(NA : Not Applicable)

17. INDICATION(S) FOR USE

1) PRODUCT USED FOR UNKNOWN INDICATION [10070592 - Product used for unknown indication]

18. THERAPY DATE(S) (from/to)	19. THERAPY DURATION
??/??/??	Unkn

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
Unkn

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER

Name : Bausch Health
400 Somerset Corporate Boulevard
Bridgewater, NJ, UNITED STATES OF AMERICA
Submission_ICSR_BHC@bauschhealth.com

24.REPORT NULLIFIED	24b. MFR CONTROL NO.
☐ YES ☐ NO	BH-2025-016303
24c. DATE RECEIVED BY MANUFACTURER: 13/Aug/2025	24d. REPORT SOURCE: ☐ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT: 25/Aug/2025	25a. REPORT TYPE: ☑ INITIAL ☐ FOLLOWUP

= Continuation attached sheet(s)..

Continuation Sheet for CIOMS report

1a. COUNTRY

DOMINICAN REPUBLIC

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

Event Description :

This non-serious spontaneous case was received on 13-Aug-2025 from a Consumer or other non health professional via sales representative and concerned a patient of an unknown age and male gender.

Concurrent conditions: Not Reported

Medical history: Not Reported

Concomitant medications: Not Reported

Past medications: Not Reported

Company suspect products include: CARDISPAN (Levocarnitine), unknown strength/unit Solution (Batch number: 401761; Expiry Date: not reported) Start date not provided, Stop date not provided, administered via Oral route for PRODUCT USED FOR UNKNOWN INDICATION.

On an unknown date, the patient experienced a strong underarmp odor after administration of CARDISPAN (Levocarnitine) Solution prescribed by a physician as unknown treatment. The treatment was not de-challenged; hence it was no changed to another drug. The patient did not receive any corrective treatment for adverse event. The patient was recovered on unknown date and it was unknown if patient had sequels. No more information is provided.

Reported Term (Preferred Term): Onset Date-Cessation Date; Seriousness; Outcome:
STRONG UNDERARMP ODOR (Skin odour abnormal): unknown - unknown; non-serious; Recovered/Resolved.

Action taken with company suspect product in response to the event, Dechallenge and Rechallenge:
CARDISPAN/STRONG UNDERARMP ODOR: Dose not changed; Not applicable; Not Applicable

Therapy status of CARDISPAN at the time of reporting was unknown.

Reporter's causality assessment:
CARDISPAN/STRONG UNDERARMP ODOR: Possible

Internal reference number included: Local PV reference number: IQF/GROSS/00004/2025.

Company Remarks (Sender's Comments) :

Version 0 (13-Aug-2025):

The event Skin odour abnormal is assessed as non-serious. Skin odour abnormal is assessed as possibly related to CARDISPAN.

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

Product-Reaction Level

1) Drug	: CARDISPAN
Active Substance	: LEVOCARNITINE
Drug Characterization	: Suspect
Form of Admin	: Solution
Lot Number	: 401761
Route of Admin	: Oral
Indications	: PRODUCT USED FOR UNKNOWN INDICATION [10070592 - Product used for unknown indication]
Action(s) Taken With Drug	: Dose not changed

Causality

1) STRONG UNDERARMP ODOR (Body odour - 10005902, Skin odour abnormal - 10040904)

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

Labeling :

Continuation Sheet for CIOMS report

1) STRONG UNDERARMP ODOR
CORE Labeled