SUSPECT ADVERSE REACTION REPORT

BH-2025-016855

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) DIARRHEA (Diarrhea (10012727), Diarrhoea (10012735))
Recovered/Resolved

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) CARDISPAN (LEVOCARNITINE) (Suspect) (1 Gram, Tablet)(Unknown)

Cont..

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

15. DAILY DOSE(S)

Unkn

16. ROUTE(S) OF ADMINISTRATION

1) Oral

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

(NA : Not Applicable)

17. INDICATION(S) FOR USE

1) DIALYSIS [10061105 - Dialysis]

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

1) CHRONIC KIDNEY DISEASE (10064848, Chronic kidney disease) (Continuing: Yes)

Cont..

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-2025-016855
24c. DATE RECEIVED BY MANUFACTURER: 27/Aug/2025	24d. REPORT SOURCE: ☐ STUDY ☐ LITERATURE ☑ HEALTH PROFESSIONAL
DATE OF THIS REPORT: 08/Sep/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 27-Aug-2025 from a physician via sales representative and concerned a patient of unknown age and male gender.

Concurrent conditions: CHRONIC KIDNEY DISEASE

Medical history: Not Reported

Concomitant medications: Unspecified medication for chronic kidney disease.

Past medications: Not Reported

History of Allergy: None

Company suspect products include: CARDISPAN (Levocarnitine), Tablet (Batch number: unknown; Expiry Date: not reported) Start date not provided, stop date not provided, administered via Oral route for DIALYSIS.

The patient with no history of comorbidities reported experienced diarrhea after administration of Cardispan (Levocarnitine) tablet prescribed by a physician as treatment for Dialysis. It was stated that patient took Cardispan Tablets and Injectable Solution (without exceeding the maximum dose of 5 g per day). The treatment was not de-challenged; hence it was not changed to another drug. The patient did not receive any corrective treatment for adverse event. The patient resolved from diarrhea (it was unknown if patient had sequels).

Reported Term (Preferred Term): Onset Date-Cessation Date; Seriousness; Outcome:
DIARRHEA (Diarrhoea): unknown - unknown; non-serious; Recovered/Resolved.

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

Final therapy status: The patient was using Cardispan at the time of reporting.

Reporter's causality assessment:
CARDISPAN/DIARRHEA: Possible

This case is cross-referenced to DO-BAUSCH-BH-2025-016856 due to Same patient.

Internal reference number included local PV number: IQF/GROSS/00005/2025.

Company Remarks (Sender's Comments) :

Version 0 (27-Aug-2025):
The event Diarrhoea is assessed as non-serious. Diarrhoea 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 Strength	: 1 Gram
Form of Admin	: Tablet
Lot Number	: Unknown
Route of Admin	: Oral
Indications	: DIALYSIS [10061105 - Dialysis]
Action(s) Taken With Drug	: Dose not changed

Causality

1) DIARRHEA (Diarrhea - 10012727, Diarrhoea - 10012735)
Causality as per reporter : Possible

Continuation Sheet for CIOMS report

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

Labeling :

1) DIARRHEA
CORE Labeled

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

Dosage Text :

Drug 1 :CARDISPAN

1) without exceeding the maximum dose of 5 g per day

23. OTHER RELEVANT HISTORY (Continuation...)

Medical History And Concurrent Conditions :

Patient had no allergies