SUSPECT ADVERSE REACTION REPORT

BH-2025-016302

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	Female	??/??/??	??/??/??	??/??/??	

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

MedDRA Version : v.28.0

1) HEAT SENSATION DURING THE FIRST MINUTES AFTER ADMINISTRATION OF FITOESTIMULINA (Sensation of heat (10039999), Feeling hot (10016334))

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) FITOESTIMULINA (PHENOXYETHANOL) (Suspect) (Cream)(Unknown) Cont..

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

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

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-2025-016302
24c. DATE RECEIVED BY MANUFACTURER: 13/Aug/2025	24d. REPORT SOURCE: ☐ STUDY ☐ LITERATURE ☑ HEALTH PROFESSIONAL
DATE OF THIS REPORT: 22/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 Physician via a sales representative and concerned a patient of unknown age and female gender.

Concurrent conditions: Not Reported

Medical history: Not Reported

Concomitant medications: Not Reported

Past medications: Not Reported

Company suspect products include: FITOESTIMULINA, Cream (Batch number: unknown; Expiry Date: not reported) Start date not provided, Stop date not provided, administered via Topical route for PRODUCT USED FOR UNKNOWN INDICATION.

On unknown date patient with no history of comorbidities experienced heat sensation during the first minutes after administration of Fitoestimulina. Patient was recovered on unknown date and it was unknown if patient had sequels.

Reported Term (Preferred Term): Onset Date-Cessation Date; Seriousness; Outcome:
HEAT SENSATION DURING THE FIRST MINUTES AFTER ADMINISTRATION OF FITOESTIMULINA(Feeling hot):unknown - unknown; non-serious; Recovered/Resolved.

Action taken with company suspect product in response to the event, Dechallenge and Rechallenge:
FITOESTIMULINA/HEAT SENSATION DURING THE FIRST MINUTES AFTER ADMINISTRATION OF FITOESTIMULINA: Unknown; Not applicable; Not Applicable

Final therapy status:
FITOESTIMULINA: Unknown

Reporter's causality assessment:
FITOESTIMULINA/HEAT SENSATION DURING THE FIRST MINUTES AFTER ADMINISTRATION OF FITOESTIMULINA: Possible

Internal reference number included: Local PV reference number: IQF/GROSS/00003/2025.

Company Remarks (Sender's Comments) :

Version 0 (13-Aug-2025):

The event Feeling hot is assessed as non-serious. Feeling hot is assessed as possibly related to FITOESTIMULINA.

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

Product-Reaction Level

1) Drug	: FITOESTIMULINA
Active Substance	: 1) PHENOXYETHANOL 2) TRITICUM VULGARE
Drug Characterization	: Suspect
Form of Admin	: Cream
Lot Number	: Unknown
Route of Admin	: Topical
Indications	: PRODUCT USED FOR UNKNOWN INDICATION [10070592 - Product used for unknown indication]
Action(s) Taken With Drug	: Unknown

Causality

1) HEAT SENSATION DURING THE FIRST MINUTES AFTER ADMINISTRATION OF FITOESTIMULINA (Sensation of heat - 10039999, Feeling hot - 10016334)

Causality as per reporter	: Possible
Causality as per Mfr	: Possible

Continuation Sheet for CIOMS report

DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) HEAT SENSATION DURING THE FIRST MINUTES AFTER ADMINISTRATION OF FITOESTIMULINA
CORE UnLabeled

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

Dosage Text :

Drug 1 :FITOESTIMULINA

1) Frequency: 2 times for week for 3 weeks