CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I.REACTION INFORMATION

1.PATIENT INITIALS (first, last)	1a.COUNTRY	2.DATE OF BIRTH Day	Month	Year	2a. AGE Years	3. SEX	4-6 REACTION ONSET Day	Month	Year
MAAN	Guatemala	??	??	??	48	F	21	MAY	2025

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

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

NAUSEA (Nausea, Nausea) [v.28.0] - Recovered/resolved
ABDOMINAL PAIN (Abdominal pain, Abdominal pain) [v.28.0] - Recovered/resolved
THE PATIENT REFERRED THAT THE CAPSULE WAS IN BAD CONDITION (Product quality complaint, Product quality issue) [v.28.0] - Unknown
Case level outcome :Recovered/resolved

This non-serious spontaneous case was received on 02/Jun/2025 from a physician via sales representative and concerned a patient of 48 years age and female gender.

Concurrent conditions: Not provided
Concomitant medications: Not provided
Past medications: Not provided
Medical history: Not provided

Cont...

II.SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
ZERPYCO DUO(DIMETHICONE, PINAVERIUM BROMIDE)(Capsule),427826

20.DID REACTION ABATE AFTER STOPPING DRUG?
☒ YES ☐ NO ☐ NA

15. DAILY DOSE(S)
2 capsule daily, 100/300mg

16. ROUTE(S) OF ADMINISTRATION
Oral

21.DID REACTION REAPPEAR AFTER REINTRODUCTION?
☐ YES ☐ NO ☒ NA

17. INDICATION(S) FOR USE
Irritable bowel syndrome [v.28.0]

18. THERAPY DATES(from/to)
14/MAY/2025 - 24/MAY/2025

19. THERAPY DURATION
11 Days

III.CONCOMITANT DRUG(S) AND HISTORY

22.CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
Concomitant Drug Not Used

23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergics, pregnancy with last month of period, etc.)
None

IV.MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
Bausch Health Companies Inc
Global Pharmacovigilance Risk Management
Bausch Health Companies Inc, 400 Somerset Corporate Boulevard
Cont...

24b. MFR. CONTROL NO.
BL-2025-007043/v0(0)

24c. DATE RECEIVED BY MANUFACTURER
02/JUN/2025

24d. REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ AUTHORITY
☒ HEALTH PROFESSIONAL ☒ OTHER Cont...

DATE OF THIS REPORT
16/JUN/2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOW UP

Company Remarks (Sender's comments) :
Version 0 (02/Jun/2025):
The event(s) Nausea, Abdominal pain, Product quality issue are assessed as non-serious. Abdominal pain and Nausea are assessed as Possibly related to Zerpyco duo. The causality for Product quality issue with respect to Zerpyco duo is Not assessable.

Initial Reporter:
PRIVACY
Guatemala

Cont... = Continuation attached sheet(s)

Bausch Health Companies Inc
Global Pharmacovigilance Risk Management
Bausch Health Companies Inc
400 Somerset Corporate Boulevard
Bridgewater,NJ

Continuation Sheet for CIOMS report

Mfr. Control No. :BL-2025-007043/v0(0)

Reaction Information (Cont...)

Seq. No.	:	1
Reaction	:	NAUSEA (Nausea, Nausea) [v.28.0]
Start Date	:	21/May/2025
Stop Date	:	24/May/2025
Duration	:	4 D
Seq. No.	:	2
Reaction	:	ABDOMINAL PAIN (Abdominal pain, Abdominal pain) [v.28.0]
Start Date	:	21/May/2025
Stop Date	:	24/May/2025
Duration	:	4 D
Seq. No.	:	3
Reaction	:	THE PATIENT REFERRED THAT THE CAPSULE WAS IN BAD CONDITION (Product quality complaint, Product quality issue) [v.28.0]
Start Date	:	21/May/2025
Stop Date	:	??/??/??
Duration	:	Unkn

Describe Reaction(s)(Include relevant test/lab data) (Cont...)

Company suspect products include:
Zerpyco duo (Pinaverium bromide/Dimethicone), unknown strength/unit, capsule (Batch number: 427826; Expiry Date: /OCT/2026) started on 14/May/2025, stopped on 24/May/2025, oral, at a dosage of unit dose unknown, unknown frequency for Irritable bowel syndrome.

On 02/Jun/2025, it was reported that the patient experienced nausea and abdominal pain during the treatment with Zerpyco-Duo (Pinaverium bromide / Dimethicone) Capsule (Dose and frequency: 2 capsules daily. Oral route. Batch number: 427826; expiry not reported Oct/26), prescribed by a physician as treatment for irritable bowel syndrome (IBS). The patient referred that the capsule was in bad condition (product quality complaint). The treatment was discontinued but it was not changed to another drug. The patient did not receive any corrective treatment for the adverse event. No concomitants treatment was reported. At the time of the report, the patient was recovered. (It was unknown if patient had sequels).

Reported Term (Preferred Term): Onset Date-Cessation Date; Seriousness; Outcome:
Nausea (Nausea): 21/May/2025-24/May/2025; non-serious; Recovered/resolved.
Abdominal pain (Abdominal pain): 21/May/2025-24/May/2025; non-serious; Recovered/resolved.
The patient referred that the capsule was in bad condition (Product quality issue): 21/May/2025-unknown; non-serious; Unknown.

Action taken with company suspect product in response to the event, Dechallenge and Rechallenge:
Zerpyco duo/Nausea: Drug discontinued; Positive; Not Applicable.
Zerpyco duo/Abdominal pain: Drug discontinued; Positive; Not Applicable.
Zerpyco duo/The patient referred that the capsule was in bad condition: Not Applicable; Not Applicable; Not Applicable.

Final therapy status:
Zerpyco duo: Drug no longer administered.

Reporter causality assessment:
Zerpyco duo/Nausea: Possible.
Zerpyco duo/Abdominal pain: Possible.
Zerpyco duo/The patient referred that the capsule was in bad condition: Not Reported.

Internal reference number: IQF/TECNO/00001/2025.

Suspect Products (Cont...)

Product-Reaction level

Seq.No.	:	1
Drug	:	ZERPYCO DUO(DIMETHICONE, PINAVERIUM BROMIDE)(Capsule)

Causality

1) NAUSEA (Nausea, Nausea) [v.28.0]

Action(s) taken with drug	:	Drug discontinued
Outcome after Change in dose	:	Complete recovery
Causality as per reporter (Drug/Vaccine)	:	Possible
Causality as per Mfr.(Drug/Vaccine)	:	Possible
Dechallenge	:	+ve
Rechallenge	:	N/A

2) ABDOMINAL PAIN (Abdominal pain, Abdominal pain) [v.28.0]

Action(s) taken with drug	:	Drug discontinued
Outcome after Change in dose	:	Complete recovery
Causality as per reporter (Drug/Vaccine)	:	Possible
Causality as per Mfr.(Drug/Vaccine)	:	Possible
Dechallenge	:	+ve
Rechallenge	:	N/A

3) THE PATIENT REFERRED THAT THE CAPSULE WAS IN BAD CONDITION (Product quality complaint, Product quality issue) [v.28.0]

Action(s) taken with drug	:	Not Applicable
Outcome after Change in dose	:	Not applicable
Causality as per reporter (Drug/Vaccine)	:	Not Reported
Causality as per Mfr.(Drug/Vaccine)	:	Not assessable

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Continuation Sheet for CIOMS report

Mfr. Control No. :BL-2025-007043/v0(0)

Dechallenge	:	N/A
Rechallenge	:	N/A

Name and Address of Manufacturer (Cont...)

Bausch Health Companies Inc
Global Pharmacovigilance Risk Management
Bausch Health Companies Inc, 400 Somerset Corporate Boulevard
Bridgewater, NJ

Report source (Cont...)

Spontaneous