SUSPECT ADVERSE REACTION REPORT

2025-100976(0)

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	PANAMA	Unknown	Unknown	Unknown	Unknown	Male	Unknown	Unknown	2025	

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

MedDRA Version : v.28.0

1) VOMITING (Vomiting (10047700), Vomiting (10047700))
(//2025 -) - Unknown

- ☐ 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) Opdivo (NIVOLUMAB) (Suspect) (Solution for injection)(Unknown)

Cont..

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

15. DAILY DOSE(S)

Unknown

16. ROUTE(S) OF ADMINISTRATION

1) Intravenous (not otherwise specified)

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

(NA : Not Applicable)

17. INDICATION(S) FOR USE

1) Gastric cancer [10017758 - Gastric cancer]

18. THERAPY DATE(S) (from/to)	19. THERAPY DURATION
1) (//2025 - Unknown)	Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

1)Folfox(FLUOROURACIL)

Cont..

23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

MedDRA Version : v.28.0
Unknown

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER

Name : BMS
UNITED STATES OF AMERICA
aepbusinessprocess@bms.com

24.REPORT NULLIFIED	24b. MFR CONTROL NO.
☐ YES ☐ NO	2025-100976(0)
24c. DATE RECEIVED BY MANUFACTURER: 16/Jul/2025	24d. REPORT SOURCE: ☐ STUDY ☐ LITERATURE ☑ HEALTH PROFESSIONAL
DATE OF THIS REPORT: 18/Jul/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 :

This report was received by business partner Adium Pharma S.A. (formerly Tecnofarma) (reference number: PA-ADIUM-PA-0075-20250716) on 16-Jul-2025 and forwarded to BMS on 16-Jul-2025. The spontaneous case was reported by a Physician and describes the occurrence of VOMITING in a male patient who received NIVOLUMAB solution for injection for Gastric cancer.

Folfox was reported as CONCOMITANT MEDICATION.

On 2025, the patient was started on intravenous NIVOLUMAB 100mg. VOMITING occurred on 2025.

The reporter saw no causal relationship between VOMITING and NIVOLUMAB. The doctor commented that the patient was not tolerating chemotherapy and would adjust the Folfox regimen.

Further company follow-up with the reporter is not possible as the physician does not agree to be contacted for future follow-up.

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

Product-Reaction Level

1) Drug	:	Opdivo
Active Substance	:	1) NIVOLUMAB
Drug Characterization	:	Suspect
Form of Admin	:	1) Solution for injection
Lot Number	:	1) Unknown
Route of Admin	:	1) Intravenous (not otherwise specified)
Indications	:	1) Gastric cancer [10017758 - Gastric cancer]
Therapy Dates	:	1) From : //2025 To :Unknown
Action(s) Taken With Drug	:	Unknown

Causality

1) VOMITING (Vomiting - 10047700, Vomiting - 10047700)

Causality as per reporter	:	Not Related
Causality as per Mfr	:	Not Related
DeChallenge	:	Unknown

Labeling :

1) VOMITING

CORE	Labeled

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

Dosage Text :

Drug 1 :OPDIVO

1) 100MG x 1 INY x 1 FCO

22.CONCOMITANT DRUG(S) (Continuation...)

1). Drug	:	Folfox
Active Substance	:	1) FLUOROURACIL
		2) FOLINIC ACID
		3) OXALIPLATIN
Form Strength	:	
Form of Admin	:	1) Unknown
Route of Admin	:	1) Unknown
Indications	:	1) PRODUCT USED FOR UNKNOWN INDICATION [10070592 - Product used for unknown indication]

Primary Reporter:

Physician

PANAMA