SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET Day	Month	Year
PRIVACY	GUATEMALA		PRIVACY		79 Years	Female	48.00 kg	03	SEP	2024

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

Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)	Product	Serious	Listed	Reporter Causality	Company Causality
Nauseas [Nausea]	IMFINZI	No	No	Related	Related
i have to get up twice at night to pee." [Nocturia]	IMFINZI	No	No	Related	Related
Nocturnal Diuresis [Polyuria]	IMFINZI	No	No	Related	Related

(Continued on Additional Information Page)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
- ☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING
- ☐ CONGENITAL ANOMALY
- ☐ OTHER

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) IMFINZI (DURVALUMAB) Infusion
(Continued on Additional Information Page)

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

15. DAILY DOSE(S)
#1) UNK, q4w

16. ROUTE(S) OF ADMINISTRATION
#1) Intravenous use

17. INDICATION(S) FOR USE
#1) Cancer of the common bile duct (Bile duct cancer)
(Continued on Additional Information Page)

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

18. THERAPY DATES(from/to)
#1) MAY-2024 / Ongoing

19. THERAPY DURATION
#1) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) Ursodeoxycholic acid (Ursodeoxycholic acid) ; Unknown

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

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Indication	Bile duct cancer (Bile duct cancer)
Unknown to Ongoing	Indication	Gallbladder cancer (Gallbladder cancer)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
AstraZeneca
Serban Ghiorghiu
1 Medimmune Way
Gaithersburg, Maryland 20878 UNITED STATES
Phone: +1 301-398-0000

26. REMARKS
World Wide #: GT-ASTRAZENECA-202409CAM002444GT
Study ID: PSP-23269
Case References: GT-AstraZeneca-CH-00708722A

24b. MFR CONTROL NO.
202409CAM002444GT

24c. DATE RECEIVED BY MANUFACTURER
09-JUN-2025

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

DATE OF THIS REPORT
11-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.
NAME AND ADDRESS WITHHELD.
NAME AND ADDRESS WITHHELD.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Case Description: A solicited report has been received from a consumer in Patient Support Program. The report concerns a female elderly patient born in 1944 (age 79 years, height 145 cm, weight 48 kg).

No medical history was reported.

Concomitant medication included Ursodeoxycholic Acid.

The patient started treatment with Imfinzi (durvalumab) UNK, q4w, Intravenous use, during MAY-2024 for cancer of the common bile duct and cancer of the gallbladder.

On 03-SEP-24, the patient experienced nauseas (preferred term: Nausea). On an unknown date, the patient experienced i have to get up twice at night to pee." (preferred term: Nocturia) and nocturnal diuresis (preferred term: Polyuria).

The dose of Imfinzi (durvalumab) was not changed.

The patient recovered from the event(s) nauseas after 1 on 03-SEP-2024. At the time of reporting, the event i have to get up twice at night to pee." and nocturnal diuresis was ongoing.

The events were considered non-serious.

The reporter considered that there was a reasonable possibility of a causal relationship between Imfinzi and the following event(s): i have to get up twice at night to pee.", nauseas and nocturnal diuresis.
The company physician considered that there was a reasonable possibility of a causal relationship between Imfinzi and the following event(s): i have to get up twice at night to pee.", nauseas and nocturnal diuresis.

Follow-up of insignificant information received by AstraZeneca/MedImmune 09-Oct-2024 from consumer: Patient details updated. Concomitant medication added. Narrative updated.

Summary of follow-up information received by AstraZeneca on 09-Jun-2025 from consumer via solicited source: study ID added, events of I have to get up twice at night to pee and Nocturnal Diuresis added. Non-significant correction 11-Jun-2025: country of patient added, duplicate reporters deleted, Correspondence contact reporter added, lot number of Imfinzi corrected, concomitant drug information corrected, lab data deleted.

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#1) IMFINZI (DURVALUMAB) Infusion; Regimen #1	UNK, q4w; Intravenous use	Cancer of the common bile duct (Bile duct cancer) Cancer of the gallbladder (Gallbladder cancer)	MAY-2024 / Ongoing; Unknown