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		Unk	Female	Unk			2023

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
Dizziness [Dizziness]	OLAPARIB	No	Yes	Related	Related
Canker Sores oral [Aphthous ulcer]	OLAPARIB	No	Yes	Related	Related
Náuseas [Nausea]	OLAPARIB	No	Yes	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) OLAPARIB (OLAPARIB) Tablet

15. DAILY DOSE(S)
#1) 600 milligram

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

17. INDICATION(S) FOR USE
#1) OVARIAN CANCER (Ovarian cancer)

18. THERAPY DATES(from/to)
#1) DEC-2023 / Ongoing

19. THERAPY DURATION
#1) Unknown

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

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

III. CONCOMITANT DRUG(S) AND HISTORY

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

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	Ovarian cancer (Ovarian cancer)
Unknown to Ongoing	Current Condition	Arterial hypertension (Hypertension)

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-202505CAM005337GT
Study ID: PSP-23269
Case References: GT-AstraZeneca-CH-00865717A

24b. MFR CONTROL NO.
202505CAM005337GT

24c. DATE RECEIVED BY MANUFACTURER
22-JUL-2025

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

DATE OF THIS REPORT
23-JUL-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

25b. NAME AND ADDRESS OF REPORTER
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 patient born in 1963.

The patient’s past and current medical history included arterial hypertension (ongoing).

Past drug therapy included Candesartan.

The patient started treatment with Olaparib (olaparib) 600 milligram, Oral use, during DEC-2023 for ovarian cancer.

During 15-JUN-23, the patient experienced canker sores oral (preferred term: Aphthous ulcer). During 15-DEC-23, the patient experienced dizziness (preferred term: Dizziness) and náuseas (preferred term: Nausea).

The dose of Olaparib (olaparib) was not changed.

The outcome of the event(s) of dizziness and náuseas was unknown. The outcome of the event(s) of canker sores oral was unknown.

The events were considered non-serious.

The reporter considered that there was a reasonable possibility of a causal relationship between Olaparib and the following event(s): canker sores oral, dizziness and náuseas.
The company physician considered that there was a reasonable possibility of a causal relationship between Olaparib and the following event(s): canker sores oral, dizziness and náuseas.

Case received without translated source documents. Case was processed based on the available populated data and the AOSE comments by selection Albanian language to access the local narrative in English.

Summary of follow up information received by AstraZeneca/MedImmune on 22-Jul-2025 from consumer via Patient Support Program report: New event 'Nausea' were added, narrative updated.

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown	Historical Drug	CANDESARTAN (Candesartan); Drug Indication: Drug use for unknown indication (Product used for unknown indication)