

# SUSPECT ADVERSE REACTION REPORT

## I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) <b>PRIVACY</b>	1a. COUNTRY <b>GUATEMALA</b>	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year				Day	Month	Year	
		<b>PRIVACY</b>			<b>Unk</b>	<b>Female</b>	<b>Unk</b>			<b>2023</b>	

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 in the mouth [Aphthous ulcer]	OLAPARIB	No	Yes	Related	Related

(Continued on Additional Information Page)

☐ 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		20. DID REACTION ABATE AFTER STOPPING DRUG?  <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
15. DAILY DOSE(S) #1 ) 300 milligram, q12h	16. ROUTE(S) OF ADMINISTRATION #1 ) Oral use	
17. INDICATION(S) FOR USE #1 ) OVARIAN CANCER (Ovarian cancer)		21. DID REACTION REAPPEAR AFTER REINTRODUCTION?  <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
18. THERAPY DATES(from/to) #1 ) 2023 / 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)		
23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)		
From/To Dates Unknown to Ongoing	Type of History / Notes Indication Current Condition	Description Ovarian cancer (Ovarian cancer) Arterial hypertension (Hypertension)

## IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER AstraZeneca Serban Ghiorgiu 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. <b>202505CAM005337GT</b>	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.  NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER <b>08-MAY-2025</b>	24d. REPORT SOURCE <input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL <input type="checkbox"/> OTHER:	
DATE OF THIS REPORT <b>12-MAY-2025</b>	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

12-May-2025 04:00

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**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) 300 milligram q12h, Oral use, during 2023 for ovarian cancer.

During 15-JUN-23, the patient experienced canker sores in the mouth (preferred term: Aphthous ulcer) and dizziness (preferred term: Dizziness).

The dose of Olaparib (olaparib) was not changed.

The outcome of the event(s) of canker sores in the mouth and dizziness 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 in the mouth and dizziness.

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

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.

**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)