

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY GUATEMALA	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	
		PRIVACY			Unk	Female	Unk			2025	

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
AFTER I TAKE THE MEDICATION I GET A MILD BODY ACHES [Pain]	OLAPARIB	No	No	Related	Related
AND FEELING OF FATIGUE SINCE I STARTED TAKING THE MEDICATION THIS HAPPENS AND IT HASN'T GONE AWAY [Fatigue]	OLAPARIB	No	Yes	Related	Related
HER CHOLESTEROL LABORATORIES WERE HIGH [Blood cholesterol increased]	OLAPARIB	No	No	Not Applicable	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 Cyst (Ovarian cyst)		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) 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 Unknown to Ongoing	Type of History / Notes Indication Indication	Description Ovarian cancer (Ovarian cancer) Ovarian cyst (Ovarian cyst)

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-202505CAM004617GT Study ID: PSP-23269 Case References: GT-AstraZeneca-CH-00865252A
	24b. MFR CONTROL NO. 202505CAM004617GT	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD. NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 07-MAY-2025	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 13-MAY-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

13-May-2025 05:34

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 1966.

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Olaparib (olaparib) 300 milligram q12h, Oral use, on an unknown date for ovarian cyst.

During 15-JUN-25, the patient experienced after i take the medication i get a mild body aches (preferred term: Pain) and and feeling of fatigue since i started taking the medication this happens and it hasn't gone away (preferred term: Fatigue). On an unknown date, the patient experienced her cholesterol laboratories were high (preferred term: Blood cholesterol increased).

The dose of Olaparib (olaparib) was not changed.

The outcome of the event(s) of after i take the medication i get a mild body aches, and feeling of fatigue since i started taking the medication this happens and it hasn't gone away and her cholesterol laboratories were high was unknown.

The events were considered non-serious.

The reporter did not assess causality for her cholesterol laboratories were high. The reporter considered that there was a reasonable possibility of a causal relationship between Olaparib and the following event(s): after i take the medication i get a mild body aches and and feeling of fatigue since i started taking the medication this happens and it hasn't gone away.

The company physician considered that there was a reasonable possibility of a causal relationship between Olaparib and the following event(s): after i take the medication i get a mild body aches, and feeling of fatigue since i started taking the medication this happens and it hasn't gone away and her cholesterol laboratories were high.

Laboratory values are available.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Blood cholesterol High		