

## SUSPECT ADVERSE REACTION REPORT

## I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) <b>PRIVACY</b>	1a. COUNTRY <b>COSTA RICA</b>	2. DATE OF BIRTH			2a. AGE <b>66</b> Years	3. SEX <b>Female</b>	3a. WEIGHT <b>Unk</b>	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year				Day	Month	Year	
			<b>PRIVACY</b>					<b>30</b>	<b>MAY</b>	<b>2025</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				<input type="checkbox"/> PATIENT DIED  <input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION <input type="checkbox"/> INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY  <input type="checkbox"/> LIFE THREATENING <input type="checkbox"/> CONGENITAL ANOMALY  <input type="checkbox"/> OTHER
rash on face [Rash]		OSIMERTINIB		No	Yes	Related	Related				
Dry throat [Dry throat]		OSIMERTINIB		No	No	Related	Related				
(Continued on Additional Information Page)											

## II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1 ) OSIMERTINIB (OSIMERTINIB) 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 ) 80 milligram, qd	16. ROUTE(S) OF ADMINISTRATION #1 ) Oral use	
17. INDICATION(S) FOR USE #1 ) lung cancer (Lung neoplasm malignant)		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 ) 17-MAY-2025 / 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	Description Lung cancer (Lung 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 #: CR-ASTRAZENECA-202506CAM002116CR Study ID: PSP-23269 Case References: CR-AstraZeneca-CH-00884486A
	24b. MFR CONTROL NO. <b>202506CAM002116CR</b>	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.  NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER <b>03-JUN-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>05-JUN-2025</b>	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

05-Jun-2025 12:22

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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 elderly patient born in 1959 (age 66 years).

No medical history was reported. No concomitant products were reported.

The patient started treatment with Osimertinib (osimertinib) 80 milligram qd, Oral use, on 17-MAY-2025 for lung cancer.

On 30-MAY-25, the patient experienced dry throat (preferred term: Dry throat) and rash on face (preferred term: Rash).

The dose of Osimertinib (osimertinib) was not changed. At the time of reporting, the event dry throat and rash on face was ongoing.

The events were considered non-serious.

The reporter considered that there was a reasonable possibility of a causal relationship between Osimertinib and the following event (s): dry throat and rash on face.

The company physician considered that there was a reasonable possibility of a causal relationship between Osimertinib and the following event(s): dry throat and rash on face.