

# 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>48</b> Years	3. SEX <b>Female</b>	3a. WEIGHT <b>Unk</b>	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION  <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
		Day	Month	Year				Day	Month	Year	
			<b>PRIVACY</b>					<b>21</b>	<b>APR</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
It breaks out first on the nose, then around the mouth and then on the cheeks [Rash]	TAGRISSO	No	Yes	Related	Related

(Continued on Additional Information Page)

## II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) <b>#1 ) TAGRISSO (OSIMERTINIB) Tablet</b>		20. DID REACTION ABATE AFTER STOPPING DRUG?  <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
15. DAILY DOSE(S) <b>#1 ) 80 milligram, qd</b>	16. ROUTE(S) OF ADMINISTRATION <b>#1 ) Oral use</b>	
17. INDICATION(S) FOR USE <b>#1 ) Lung cancer (Lung neoplasm malignant)</b>		21. DID REACTION REAPPEAR AFTER REINTRODUCTION?  <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
18. THERAPY DATES(from/to) <b>#1 ) 11-MAR-2021 / Ongoing</b>	19. THERAPY DURATION <b>#1 ) Unknown</b>	

## 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.) <table border="0"> <tr> <td>From/To Dates</td> <td>Type of History / Notes</td> <td>Description</td> </tr> <tr> <td>Unknown</td> <td>Indication</td> <td>Lung cancer (Lung cancer)</td> </tr> </table>			From/To Dates	Type of History / Notes	Description	Unknown	Indication	Lung cancer (Lung cancer)
From/To Dates	Type of History / Notes	Description						
Unknown	Indication	Lung cancer (Lung cancer)						

## IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER <b>AstraZeneca Serban Ghiorgiu 1 Medimmune Way Gaithersburg, Maryland 20878 UNITED STATES Phone: +1 301-398-0000</b>		26. REMARKS <b>World Wide #: CR-ASTRAZENECA-202504CAM024560CR Study ID: PSP-23269 Case References: CR-AstraZeneca-CH-00858512A</b>
	24b. MFR CONTROL NO. <b>202504CAM024560CR</b>	25b. NAME AND ADDRESS OF REPORTER <b>NAME AND ADDRESS WITHHELD.</b>  <b>NAME AND ADDRESS WITHHELD.</b>
24c. DATE RECEIVED BY MANUFACTURER <b>28-APR-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>02-MAY-2025</b>	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

02-May-2025 07:42

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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 adult patient born in 1976 (age 48 years).

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Tagrisso (osimertinib) 80 milligram qd, Oral use, on 11-MAR-2021 for lung cancer.

On 21-APR-25, the patient experienced it breaks out first on the nose, then around the mouth and then on the cheeks (preferred term: Rash).

The dose of Tagrisso (osimertinib) was not changed.

At the time of reporting, the event it breaks out first on the nose, then around the mouth and then on the cheeks was ongoing.

The event was considered non-serious.

The reporter considered that there was a reasonable possibility of a causal relationship between Tagrisso and the following event(s): it breaks out first on the nose, then around the mouth and then on the cheeks.

The company physician considered that there was a reasonable possibility of a causal relationship between Tagrisso and the following event(s): it breaks out first on the nose, then around the mouth and then on the cheeks.