

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY DOMINICAN REPUBLIC	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		Unk		

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
Lung problems [Lung disorder]	TAGRISSO	Yes	Yes	Not Applicable	Related
Cant breath well [Dyspnoea]	TAGRISSO	No	No	Not Applicable	Related
Dry skin [Dry skin]	TAGRISSO	No	Yes	Related	Related
Skin reactions [Skin disorder]	TAGRISSO	No	No	Related	Related
Outbreaks [Rash]	TAGRISSO	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) TAGRISSO (OSIMERTINIB) Tablet		20. DID REACTION ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input 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) (Not Coded)		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) Unknown	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	Type of History / Notes	Description
Unknown		

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 #: DO-ASTRAZENECA-202506CAM008648DO Study ID: PSP-23269 Case References: DO-AstraZeneca-CH-00889589A
	24b. MFR CONTROL NO. 202506CAM008648DO	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD. NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 11-JUN-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-JUN-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

13-Jun-2025 04:59

ADDITIONAL INFORMATION**7+13. DESCRIBE REACTION(S) continued**

Case Description: A solicited report has been received from a consumer in Patient Support Program, concerning a female patient (age not provided).

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

On an unknown date, the patient started treatment with Tagrisso (osimertinib) 80 milligram qd, Oral use.

On an unknown date, the patient experienced lung problems (preferred term: Lung disorder), outbreaks (preferred term: Rash), skin reactions (preferred term: Skin disorder), dry skin (preferred term: Dry skin) and cant breath well (preferred term: Dyspnoea).

It was unknown if any action was taken with Tagrisso (osimertinib).

The outcome of the events of cant breath well, dry skin, lung problems, outbreaks and skin reactions was unknown.

The following event was considered serious due to seriousness criteria of hospitalization: lung problems.

The following events were considered non-serious: cant breath well, dry skin, outbreaks and skin reactions.

The reporter did not assess causality for cant breath well and lung problems.

The reporter considered that there was a reasonable possibility of a causal relationship between Tagrisso and the following events: dry skin, outbreaks and skin reactions.

The company physician considered that there was a reasonable possibility of a causal relationship between Tagrisso and the following events: cant breath well, dry skin, lung problems, outbreaks and skin reactions.