

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY COSTA RICA	2. DATE OF BIRTH			2a. AGE 82 Years	3. SEX Male	3a. WEIGHT Unk	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year				Day	Month	Year	
			PRIVACY					05	JUN	2025	

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)

Other Serious Criteria: Medically Significant

Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)	Product	Serious	Listed	Reporter Causality	Company Causality
Intense diarrhea, very strong, my whole body was covered in poop [Diarrhoea]	TAGRISSO	Yes	Yes	Related	Related
Dizziness [Dizziness]	TAGRISSO	Yes	No	Related	Related
Infarto [Infarction]	TAGRISSO	Yes	No	Unknown	Unknown

(Continued on Additional Information Page)

☒ PATIENT DIED
Date: 26-JUN-2025
☐ 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 checked="" type="checkbox"/> NA
15. DAILY DOSE(S) #1) Unknown	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) 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 Type of History / Notes Description Unknown to Ongoing Indication Lung cancer (Lung cancer)		

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 #: CR-ASTRAZENECA-202506CAM004760CR Study ID: PSP-23269 Case References: CR-AstraZeneca-CH-00886726A
	24b. MFR CONTROL NO. 202506CAM004760CR	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD. NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 26-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 01-JUL-2025	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> FOLLOWUP: 1	

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 male elderly patient born in 1942 (age 82 years).

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Tagrisso (osimertinib) 80 milligram qd, Oral use, on an unknown date for lung cancer.

On 05-JUN-25, the patient experienced intense diarrhea, very strong, my whole body was covered in poop (preferred term: Diarrhoea) and dizziness (preferred term: Dizziness). On 26-JUN-25, the patient experienced infarto (preferred term: Infarction).

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

The patient died from the event infarto on 26-JUN-2025. At the time of reporting, the event dizziness and intense diarrhea, very strong, my whole body was covered in poop was ongoing.

The patient died on 26-JUN-2025. It is not known whether an autopsy was performed. The cause of death was unknown.

The events were considered serious (Death and Medically Significant).

The reporter did not assess causality for infarto. The reporter considered that there was a reasonable possibility of a causal relationship between Tagrisso and the following event(s): dizziness and intense diarrhea, very strong, my whole body was covered in poop.

The company physician considered that there was a reasonable possibility of a causal relationship between Tagrisso and the following event(s): dizziness and intense diarrhea, very strong, my whole body was covered in poop.

Summary of follow up information received by AstraZeneca on 30-JUN-2025 from consumer via solicited source: Event infarto added with outcome as fatal on 26-JUN-2025. Narrative updated.

Company Clinical Comment: Fatal event of infarction and serious event of dizziness are not listed in the company core data sheet of osimertinib. Underlying lung cancer could be risk factor for events. Age of patient could be confounding. Due to limited information on the exact circumstances leading to the events, start date of suspect drug, previous neurological complications (if any), specific risk factors, baseline/ interim etiological and complete diagnostic work up, relevant medical history, concurrent conditions, concomitant medications, the evaluation did not find evidence to exclude a causal relationship between the events and suspect drug.