

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY COSTA RICA	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	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	Unk	Female	Unk	Day	Month	Year	
			PRIVACY						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
Rash all over the body [Rash]	OSIMERTINIB	No	Yes	Related	Related
Itching [Pruritus]	OSIMERTINIB	No	Yes	Related	Related
Inflammation [Inflammation]	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 {Lot # Unknown}		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) 24-MAR-2025 / 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 Unknown to Ongoing	Type of History / Notes Indication	Description 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-202506CAM000628CR Study ID: PSP-23269 Case References: CR-AstraZeneca-CH-00883039A
	24b. MFR CONTROL NO. 202506CAM000628CR	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD. NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 08-JUL-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 10-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 female patient born in 1966.

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Osimertinib (osimertinib) (batch number(s) Unknown) 80 milligram qd, Oral use, on 24-MAR-2025 for lung cancer.

On an unknown date, the patient experienced itching (preferred term: Pruritus), rash all over the body (preferred term: Rash) and inflammation (preferred term: Inflammation).

The report described off-label use for Osimertinib.

At the time of reporting, the event inflammation, itching and rash all over the body 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): inflammation, itching and rash all over the body.

The company physician considered that there was a reasonable possibility of a causal relationship between Osimertinib and the following event(s): inflammation, itching and rash all over the body.

Follow-up of non-significant information received by AstraZeneca on 08-Jul-2025 from a consumer: action taken was changed from temporally withdrawn to withdrawn, narrative updated.