

# 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	3. SEX	3a. WEIGHT	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year				Day	Month	Year	
		<b>PRIVACY</b>			<b>Unk</b>	<b>Female</b>	<b>Unk</b>		<b>Unk</b>		
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			
The patient indicates that he wears glasses because a small film is growing over both eyes, completely over the right eye and almost completely over the left eye [Cataract]		OSIMERTINIB		Yes	No	Not Applicable		Related		<input type="checkbox"/> PATIENT DIED	
Her toenails and fingernails feel eaten away and infected/Patient presents with terrible fingernails and toenails [Nail infection]		OSIMERTINIB		No	Yes	Related		Related		<input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION	
(Continued on Additional Information Page)											<input type="checkbox"/> INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY
											<input type="checkbox"/> LIFE THREATENING
											<input type="checkbox"/> CONGENITAL ANOMALY
											<input checked="" type="checkbox"/> OTHER

## II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1 ) OSIMERTINIB (OSIMERTINIB) Tablet {Lot # FKZM; Exp.Dt. 31-AUG-2025} (Continued on Additional Information Page)		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 with metastasis (the area o (Continued on Additional Information Page)		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 ) 08-MAY-2024 / 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	Cancer of bronchus (Bronchial carcinoma)
Unknown to Ongoing	Indication	Lung cancer metastatic (Lung cancer metastatic)

## 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-202506CAM000580CR Study ID: PSP-23269 Case References: CR-AstraZeneca-CH-00882997A
	24b. MFR CONTROL NO. <b>202506CAM000580CR</b>	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER <b>02-JUN-2025</b>	24d. REPORT SOURCE <input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL <input type="checkbox"/> OTHER:	NAME AND ADDRESS WITHHELD.
DATE OF THIS REPORT <b>04-JUN-2025</b>	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

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

Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)	Product	Serious	Listed	Reporter Causality	Company Causality
sometimes blisters appear on her body [Blister]	OSIMERTINIB	No	No	Related	Related
pain in her knees [Arthralgia]	OSIMERTINIB	No	No	Related	Related
depression/Patient indicates that he feels sad, as if he were very depressed [Depression]	OSIMERTINIB	No	No	Related	Related
anxiety/Patient presents anxiety attacks [Anxiety]	OSIMERTINIB	No	No	Related	Not Related
Patient presents fatigue [Fatigue]	OSIMERTINIB	No	No	Related	Related
Patient feels confused [Confusional state]	OSIMERTINIB	No	No	Related	Related
Patient presents swollen joints [Joint swelling]	OSIMERTINIB	No	No	Related	Related
Patient indicates that he has mottled skin, mainly on the face [Skin discolouration]	OSIMERTINIB	No	No	Related	Related
Patient indicates that my hair is falling out [Alopecia]	OSIMERTINIB	No	Yes	Related	Related
Patient presents dryness, mostly at night [Dry skin]	OSIMERTINIB	No	Yes	Related	Related
Patient presents pain in the legs [Pain in extremity]	OSIMERTINIB	No	No	Related	Related
inflammation [Inflammation]	OSIMERTINIB	No	No	Related	Not Related
Forgetting things [Memory impairment]	OSIMERTINIB	No	No	Related	Not Related
Poor concentration [Disturbance in attention]	OSIMERTINIB	No	No	Related	Not Related
frustration [Frustration tolerance decreased]	OSIMERTINIB	No	No	Related	Not Related
difficulty walking [Gait disturbance]	OSIMERTINIB	No	No	Related	Not Related

Case Description: A solicited report has been received from a consumer in Patient Support Program, concerning a female patient born in 1969.

No medical history and concomitant products were reported.

On 08-May-2024 the patient started treatment with Osimertinib (osimertinib) (batch number(s) FKZM) (expiration date(s) 31-Aug-2025) 80 milligram qd, Oral use, for bronchial cancer and lung cancer with metastasis (the area of metastasis is not specified).

On an unknown date, the patient experienced sometimes blisters appear on her body (preferred term: Blister), her toenails and fingernails feel eaten away and infected/patient presents with terrible fingernails and toenails (preferred term: Nail infection), difficulty walking (preferred term: Gait disturbance), frustration (preferred term: Frustration tolerance decreased), poor concentration (preferred term: Disturbance in attention), forgetting things (preferred term: Memory impairment), inflammation (preferred term: Inflammation), patient presents pain in the legs (preferred term: Pain in extremity), patient presents dryness, mostly at night (preferred term: Dry skin), patient indicates that my hair is falling out (preferred term: Alopecia), patient indicates that he has mottled skin, mainly on the face (preferred term: Skin discolouration), patient presents swollen joints (preferred term: Joint swelling), patient feels confused (preferred term: Confusional state), patient presents fatigue (preferred term: Fatigue), the patient indicates that he wears glasses because a small film is growing over both eyes, completely over the right eye and almost completely over the left eye (preferred term: Cataract), anxiety/patient presents anxiety attacks (preferred term: Anxiety), depression/patient indicates that he feels sad, as if he were very depressed (preferred term: Depression) and pain in her knees (preferred term: Arthralgia).

At the time of reporting the dose of Osimertinib (osimertinib) was not changed.

At the time of reporting, the event anxiety/patient presents anxiety attacks, depression/patient indicates that he feels sad, as if he were very depressed, forgetting things, frustration, her toenails and fingernails feel eaten away and infected/patient presents with terrible fingernails and toenails, pain in her knees, patient feels confused, patient indicates that he has mottled skin, mainly on the face, patient indicates that my hair is falling out, patient presents dryness, mostly at night, patient presents fatigue, patient presents pain in the legs, patient presents swollen joints, poor concentration, sometimes blisters appear on her body and the patient indicates that he wears glasses because a small film is growing over both eyes, completely over the right eye and almost completely over the left eye was ongoing. The outcome of the event(s) of difficulty walking and inflammation was unknown.

The event the patient indicates that he wears glasses because a small film is growing over both eyes, completely over the right eye and almost completely over the left eye was updated from non-serious to serious due to important medical event as per IME list.

The reporter assessed events anxiety/patient presents anxiety attacks, depression/patient indicates that he feels sad, as if he were very depressed, difficulty walking, forgetting things, frustration, her toenails and fingernails feel eaten away and infected/patient presents with terrible fingernails and toenails, inflammation, pain in her knees, patient feels confused, patient indicates that he has mottled skin, mainly on the face, patient indicates that my hair is falling out, patient presents dryness, mostly at night, patient presents fatigue, patient presents pain in the legs, patient presents swollen joints, poor concentration and sometimes blisters appear on her body as non-serious.

The reporter did not assess causality for the patient indicates that he wears glasses because a small film is growing over both eyes, completely over the right eye and almost completely over the left eye. The reporter considered that there was a reasonable possibility of a causal relationship between Osimertinib and the following event(s): anxiety/patient presents anxiety attacks, depression/patient indicates that he feels sad, as if he were very depressed, difficulty walking, forgetting things, frustration, her toenails and fingernails feel eaten away and infected/patient presents with terrible fingernails and toenails, inflammation, pain in her knees, patient feels confused, patient indicates that he has mottled skin, mainly on the face, patient indicates that my hair is falling out, patient presents

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

dryness, mostly at night, patient presents fatigue, patient presents pain in the legs, patient presents swollen joints, poor concentration and sometimes blisters appear on her body.

The company physician did not consider that there was a reasonable possibility of a causal relationship between Osimertinib and the following event(s): anxiety/patient presents anxiety attacks, difficulty walking, forgetting things, frustration, inflammation and poor concentration. The company physician considered that there was a reasonable possibility of a causal relationship between Osimertinib and the following event(s): depression/patient indicates that he feels sad, as if he were very depressed, her toenails and fingernails feel eaten away and infected/patient presents with terrible fingernails and toenails, pain in her knees, patient feels confused, patient indicates that he has mottled skin, mainly on the face, patient indicates that my hair is falling out, patient presents dryness, mostly at night, patient presents fatigue, patient presents pain in the legs, patient presents swollen joints, sometimes blisters appear on her body and the patient indicates that he wears glasses because a small film is growing over both eyes, completely over the right eye and almost completely over the left eye.

Company Clinical Comment: Cataract is not listed in the company core data sheet of Osimertinib. Due to limited information on onset date of the event, outcome of the event, relevant medical history, circumstances surrounding the event, etiological and diagnostic workup, concurrent diseases, concomitant medications, further risk factors, family history, the evaluation did not find evidence to exclude a causal relationship between the event and the suspect drug.

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#1 ) OSIMERTINIB (OSIMERTINIB) Tablet {Lot # FKZM; Exp.Dt. 31-AUG-2025}; Regimen #1	80 milligram, qd; Oral use	Lung cancer with metastasis (the area of metastasis is not specified) (Lung cancer metastatic) bronchial cancer (Bronchial carcinoma)	08-MAY-2024 / Ongoing; Unknown