

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY COSTA RICA	2. DATE OF BIRTH Day Month Year PRIVACY	2a. AGE 40 Years	3. SEX Female	3a. WEIGHT Unk	4-6 REACTION ONSET Day Month Year FEB 2025	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION <input type="checkbox"/> PATIENT DIED <input checked="" 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 checked="" type="checkbox"/> OTHER																																			
7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data) Other Serious Criteria: Medically Significant <table><thead><tr><th>Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)</th><th>Product</th><th>Serious</th><th>Listed</th><th>Reporter Causality</th><th>Company Causality</th></tr></thead><tbody><tr><td>KNEE PAIN [Arthralgia]</td><td>OSIMERTINIB</td><td>No</td><td>No</td><td>Related</td><td>Related</td></tr><tr><td>INFLAMMATION OF THE STOMACH [Gastritis]</td><td>OSIMERTINIB</td><td>No</td><td>No</td><td>Related</td><td>Related</td></tr><tr><td>STOMACH PROBLEMS [Gastrointestinal disorder]</td><td>OSIMERTINIB</td><td>No</td><td>No</td><td>Related</td><td>Related</td></tr><tr><td>RASHES ON THE CHEST AND CHEEKS [Rash]</td><td>OSIMERTINIB</td><td>No</td><td>Yes</td><td>Related</td><td>Related</td></tr><tr><td>ACNE [Acne]</td><td>OSIMERTINIB</td><td>No</td><td>Yes</td><td>Related</td><td>Related</td></tr></tbody></table> (Continued on Additional Information Page)								Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)	Product	Serious	Listed	Reporter Causality	Company Causality	KNEE PAIN [Arthralgia]	OSIMERTINIB	No	No	Related	Related	INFLAMMATION OF THE STOMACH [Gastritis]	OSIMERTINIB	No	No	Related	Related	STOMACH PROBLEMS [Gastrointestinal disorder]	OSIMERTINIB	No	No	Related	Related	RASHES ON THE CHEST AND CHEEKS [Rash]	OSIMERTINIB	No	Yes	Related	Related	ACNE [Acne]	OSIMERTINIB	No	Yes	Related
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II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1) OSIMERTINIB (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) 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) 06-JAN-2024 / 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 to Ongoing Indication Lung cancer (Lung neoplasm malignant)		

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-2024A184539 Study ID: PSP-23269 Case References: CR-AstraZeneca-2024-270966
	24b. MFR CONTROL NO. 2024A184539	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 29-MAY-2025	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 04-JUN-2025	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> FOLLOWUP: 1	NAME AND ADDRESS WITHHELD.

(Continued on Additional Information Page)

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
"I have a bacterial infection" [Bacterial infection]	OSIMERTINIB	Yes	No	Not Applicable	Not Related
"Intense pain on my right side" [Pain]	OSIMERTINIB	Yes	No	Not Applicable	Not Related
Fever [Pyrexia]	OSIMERTINIB	Yes	No	Not Applicable	Not Related
Sensitive skin [Sensitive skin]	OSIMERTINIB	Yes	No	Not Applicable	Related
Constant urination [Pollakiuria]	OSIMERTINIB	Yes	No	Not Applicable	Not Related
Constipation [Constipation]	OSIMERTINIB	Yes	No	Not Applicable	Related
Kidney stones [Nephrolithiasis]	OSIMERTINIB	Yes	No	Not Applicable	Not Related
nails fell [Nail avulsion]	OSIMERTINIB	No	No	Related	Related
dark spots on my face [Pigmentation disorder]	OSIMERTINIB	No	No	Related	Related
they're itching me a lot [Pruritus]	OSIMERTINIB	No	Yes	Related	Related

Case Description: A solicited report has been received from a consumer in Patient Support Program concerning a female adult patient born in 1985 (age 40 years).

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

On 06-Jan-2024, the patient started treatment with Osimertinib (osimertinib) 80 milligram qd, Oral use, for lung cancer.

During 15-Feb-25, the patient experienced kidney stones (preferred term: Nephrolithiasis). On 30-Mar-25, the patient experienced i have a bacterial infection (preferred term: Bacterial infection), constipation (preferred term: Constipation), constant urination (preferred term: Pollakiuria), sensitive skin (preferred term: Sensitive skin), fever (preferred term: Pyrexia) and intense pain on my right side (preferred term: Pain). On an unknown date, the patient experienced stomach problems (preferred term: Gastrointestinal disorder), dark spots on my face (preferred term: Pigmentation disorder), nails fell (preferred term: Nail avulsion), they're itching me a lot (preferred term: Pruritus), inflammation of the stomach (preferred term: Gastritis), knee pain (preferred term: Arthralgia), acne (preferred term: Acne) and rashes on the chest and cheeks (preferred term: Rash).

The dose of Osimertinib was not changed.

The outcome of the events of kidney stones was unknown. At the time of reporting, the event i have a bacterial infection, intense pain on my right side, acne, constant urination, constipation, dark spots on my face, fever, inflammation of the stomach, knee pain, nails fell, rashes on the chest and cheeks, sensitive skin, stomach problems and they're itching me a lot was ongoing.

The reporter assessed the events of i have a bacterial infection, intense pain on my right side, fever, sensitive skin, constant urination and constipation as serious due to hospitalized criterion.

The reporter assessed the event of kidney stones as serious due to medically significant criterion.

The reporter assessed the events of acne, inflammation of the stomach, knee pain, nails fell, rashes on the chest and cheeks and stomach problems as non-serious.

The company physician assessed the events of dark spots on my face and they're itching me a lot as non-serious.

The reporter did not assess causality for i have a bacterial infection, intense pain on my right side, constant urination, constipation, fever, kidney stones and sensitive skin.

The reporter considered that there was a reasonable possibility of a causal relationship between Osimertinib and the following events: acne, dark spots on my face, inflammation of the stomach, knee pain, nails fell, rashes on the chest and cheeks, stomach problems and they're itching me a lot.

The company physician did not consider that there was a reasonable possibility of a causal relationship between Osimertinib and the following events: i have a bacterial infection, intense pain on my right side, constant urination, fever and kidney stones.

The company physician considered that there was a reasonable possibility of a causal relationship between Osimertinib and the following events: acne, constipation, dark spots on my face, inflammation of the stomach, knee pain, nails fell, rashes on the chest and cheeks, sensitive skin, stomach problems and they're itching me a lot.

Summary of follow-up information received by AstraZeneca/MedImmune on 2-Apr-2025 from Other Health Professional via solicited source: product start date updated, narrative updated.

Summary of follow-up information received by AstraZeneca/MedImmune on 29-May-2025 from Consumer via Patient Support Program source: Primary reporter consumer was added. New non-serious events Nails fell and Dark spots on my face and They're itching me a lot were added. Narrative updated.

Company Clinical Comment: Constipation and sensitive skin are not listed in the company core data sheet for Osimertinib. Underlying lung cancer could be confounding to the events. Advanced age could be contributing factor for the event. Due to limited information on the circumstances leading to events, clinical course, concomitant conditions, risk factors, relevant medical history, concomitant medication, status of underlying malignancy, detailed diagnostic and etiologic workup, the evaluation did not find the evidence to exclude a reasonable possibility of a causal relationship between the events and suspect drug.

ADDITIONAL INFORMATION

25b. Name And Address of Reporters continued
NAME AND ADDRESS WITHHELD.

NAME AND ADDRESS WITHHELD.

NAME AND ADDRESS WITHHELD.

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