SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET Day	Month	Year
PRIVACY	COSTA RICA		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
Fever [Pyrexia]	TAGRISSO	No	No	Related	Related
Diarrhea [Diarrhoea]	TAGRISSO	No	Yes	Related	Related
Itchy skin [Pruritus]	TAGRISSO	No	Yes	Related	Related
Fatigue [Fatigue]	TAGRISSO	No	No	Not Applicable	Related
My nails are rotting [Nail infection]	TAGRISSO	No	Yes	Related	Related
I get skin sores [Skin ulcer]	TAGRISSO	No	No	Related	Related
my nose sometimes bleeds [Epistaxis]	TAGRISSO	No	Yes	Related	Related

(Continued on Additional Information Page)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ 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

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)

18. THERAPY DATES(from/to)
#1) 20-JAN-2025 / Ongoing

19. THERAPY DURATION
#1) Unknown

20. DID REACTION ABATE AFTER STOPPING DRUG?
☐ YES ☐ NO ☒ NA

21. DID REACTION REAPPEAR AFTER REINTRODUCTION?
☐ YES ☐ NO ☒ NA

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) Rivotril (Clonazepam) ; Unknown
#2) Loperamide (Loperamide hydrochloride) ; Unknown

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-202502003224CR
Study ID: DMS (Disfruto Mi Salud)
Case References: CR-AstraZeneca-CH-00801654A

24b. MFR CONTROL NO.
202502CAM003224CR

24c. DATE RECEIVED BY MANUFACTURER
02-JUN-2025

24d. REPORT SOURCE
☒ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL ☐ OTHER:

DATE OF THIS REPORT
05-JUN-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.
NAME AND ADDRESS WITHHELD.
NAME AND ADDRESS WITHHELD.

Mfr. Control Number: 202502CAM003224CR

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
there are foods I cant tolerate [Food intolerance]	TAGRISSO	No	No	Related	Related
I vomit [Vomiting]	TAGRISSO	No	No	Related	Related

Case Description: A solicited report has been received from a consumer in Patient Support Program. The report concerns a female patient born in 1972.

No medical history was reported.

Concomitant medication included Rivotril and Loperamide.

The patient started treatment with Tagrisso (osimertinib) 80 milligram qd, Oral use, on 20-JAN-2025 for lung cancer.

On an unknown date, the patient experienced i vomit (preferred term: Vomiting), my nails are rotting (preferred term: Nail infection), there are foods i cant tolerate (preferred term: Food intolerance), my nose sometimes bleeds (preferred term: Epistaxis), i get skin sores (preferred term: Skin ulcer), fatigue (preferred term: Fatigue), itchy skin (preferred term: Pruritus), diarrhea (preferred term: Diarrhoea) and fever (preferred term: Pyrexia).

The dose of Tagrisso (osimertinib) was not changed.

At the time of reporting, the event fever was improving. At the time of reporting, the event diarrhea, fatigue, i get skin sores, i vomit, itchy skin, my nails are rotting, my nose sometimes bleeds and there are foods i cant tolerate was ongoing.

The events were considered non-serious.

The reporter did not assess causality for fatigue.The reporter considered that there was a reasonable possibility of a causal relationship between Tagrisso and the following event(s): diarrhea, fever, i get skin sores, i vomit, itchy skin, my nails are rotting, my nose sometimes bleeds and there are foods i cant tolerate.
The company physician considered that there was a reasonable possibility of a causal relationship between Tagrisso and the following event(s): diarrhea, fatigue, fever, i get skin sores, i vomit, itchy skin, my nails are rotting, my nose sometimes bleeds and there are foods i cant tolerate.

Summary of follow up information received by AstraZeneca/MedImmune from consumer via solicited sources on 02-Jun-2025: new events of My nails are rotting, I get skin sores, my nose sometimes bleeds, there are foods I cant tolerate and I vomit added, consumer reporter added, start date of tagrisso was updated to 20-Jan-2025 from Jan-2025, consent to contact with reporter was updated to no from yes, narrative was updated. Non-significant correction on 04-Jun-2025: verbatim of the events of fever, fatigue, itchy skin and diarrhea were updated, unknown indication of concomitant drugs removed.