SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET		
		Day	Month	Year				Day	Month	Year
PRIVACY	COSTA RICA		PRIVACY		Unk	Female	Unk		Unk	

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
Itchy throat [Throat irritation]	FASLODEX	Yes	No		
Itchy throat [Throat irritation]	Luer Pre-filled Syringe	Yes	No		
Dry cough [Cough]	FASLODEX	Yes	No		
Dry cough [Cough]	Luer Pre-filled Syringe	Yes	No		

(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) FASLODEX (FULVESTRANT) Solution for injection {Lot # Unknown}
#2) Luer Pre-filled Syringe (Luer Pre-filled Syringe) Unknown

15. DAILY DOSE(S)
#1) 500 milligram, q4w
#2)

16. ROUTE(S) OF ADMINISTRATION
#1) Intramuscular use
#2) Unknown

17. INDICATION(S) FOR USE
#1) Breast cancer (Breast cancer)
#2) Breast cancer (Breast cancer)

18. THERAPY DATES(from/to)
#1) 18-JUL-2025 / Unknown
#2) Unknown

19. THERAPY DURATION
#1) Unknown
#2) 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)

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	Breast cancer (Breast cancer)

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-202508CAM000608CR
Case References: CR-AstraZeneca-CH-00923513A

24b. MFR CONTROL NO.
202508CAM000608CR

24c. DATE RECEIVED BY MANUFACTURER
01-AUG-2025

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

DATE OF THIS REPORT
05-AUG-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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

NAME AND ADDRESS WITHHELD.

Mfr. Control Number: 202508CAM000608CR

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Case Description: A spontaneous report has been received from a physician concerning a female patient (age not provided).

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

On 18-Jul-2025, the patient started treatment with Faslodex (fulvestrant) (batch number(s) Unknown) 500 milligram q4w, Intramuscular use, for breast cancer.

It is unknown who administered Faslodex to the patient.

On an unknown date, the patient experienced itchy throat (preferred term: Throat irritation) and dry cough (preferred term: Cough).

It is unknown if any action was taken with Faslodex (fulvestrant).

The outcome of the event(s) of dry cough and itchy throat was unknown.

The reporter assessed events of itchy throat and dry cough as serious due to seriousness criteria of medically significant

Device Information:
Combination Product Report: Yes
Product As Reported: Faslodex
Brand Name: FASLODEX
Product Role:Suspect
Manufacturer Name:ASTRAZENECA
Labeled for single use:No

Company Clinical Comment: Throat irritation and cough are not listed in the company core data sheet of fulvestrant. Events has been reported in patient using luer pre-filled syringe. Events are in association with each other. Due to limited information on circumstances leading to events, situation regarding the device, events onset date and outcome, clinical course, treatment provided, predisposing risk factors, relevant medical history, concurrent conditions, concomitant medications, detailed diagnostic and etiologic workup, the evaluation did not find the evidence to suggest a causal relationship between the events, luer pre-filled syringe and suspect drug.