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
Tos [Cough]	FASLODEX	No	No	Related	
Tos [Cough]	Luer Pre-filled Syringe	No	No	Related	
Hoarseness [Dysphonia]	FASLODEX	No	No	Related	
Hoarseness [Dysphonia]	Luer Pre-filled Syringe	No	No	Related	
Dizziness [Dizziness]	FASLODEX	No	No	Related	
Dizziness [Dizziness]	Luer Pre-filled Syringe	No	No	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) FASLODEX (FULVESTRANT) Solution for injection {Lot # Unknown}
#2) Luer Pre-filled Syringe (Luer Pre-filled Syringe) Unknown

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

15. DAILY DOSE(S)
#1) Unknown
#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)

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

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

19. THERAPY DURATION
#1) Unknown
#2) 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	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-202508CAM000578CR
Case References: CR-AstraZeneca-CH-00923510A

24b. MFR CONTROL NO.
202508CAM000578CR

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

NAME AND ADDRESS WITHHELD.

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:

Mfr. Control Number: 202508CAM000578CR

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

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

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Faslodex (fulvestrant) (batch number(s) Unknown) 500 milligram q4w, Intramuscular use, on an unknown date for breast cancer.

No malfunction has been reported for the Luer Pre-filled Syringe device.

On an unknown date, the patient experienced hoarseness (preferred term: Dysphonia), tos (preferred term: Cough) and dizziness (preferred term: Dizziness).

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

The outcome of the event(s) of dizziness, hoarseness and tos was unknown.

The events were considered non-serious.

The reporter considered that there was a reasonable possibility of a causal relationship between Faslodex and the following event(s): dizziness, hoarseness and tos. The reporter considered that there was a reasonable possibility of a causal relationship between Luer Pre-Filled Syringe and the following event(s): dizziness, hoarseness and tos.

Device Information:
Combination Product Report: Yes
Product As Reported: Faslodex
Brand Name: FASLODEX
Product Role:Suspect
Device Problem code:Adverse Event Without Identified Device or Use Problem
Manufacturer Name:ASTRAZENECA
Labeled for single use:No