CIOMS FORM

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	20	MAY	2025

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
URTICARIA GLUTEUS, ABDOMEN, THIGHS, ARMS [Urticaria]	FASLODEX	No	Yes	Related	
URTICARIA GLUTEUS, ABDOMEN, THIGHS, ARMS [Urticaria]	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

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

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 20-MAY-2025 / Unknown	#1) Unknown
#2) 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-202508CAM000591CR
Case References: CR-AstraZeneca-CH-00923512A

24b. MFR CONTROL NO.
202508CAM000591CR

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:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Case Description: A spontaneous report has been received from a other health professional. 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 20-MAY-2025 for breast cancer.

A Health Care Professional administered Faslodex.

On 20-MAY-25, the patient experienced urticaria gluteus, abdomen, thighs, arms (preferred term: Urticaria).

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

The outcome of the event(s) of urticaria gluteus, abdomen, thighs, arms was unknown.

The event was considered non-serious.

The reporter considered that there was a reasonable possibility of a causal relationship between Faslodex and the following event(s): urticaria gluteus, abdomen, thighs, arms. The reporter considered that there was a reasonable possibility of a causal relationship between Luer Pre-Filled Syringe and the following event(s): urticaria gluteus, abdomen, thighs, arms.

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