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)

Other Serious Criteria: Medically Significant

Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)	Product	Serious	Listed	Reporter Causality	Company Causality
Generalised rash [Rash]	FASLODEX	Yes	Yes		
Generalised rash [Rash]	Luer Pre-filled Syringe	Yes	No		
Urticaria [Urticaria]	FASLODEX	Yes	Yes		
Urticaria [Urticaria]	Luer Pre-filled Syringe	Yes	No		
Blisters [Blister]	FASLODEX	Yes	No		
Blisters [Blister]	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

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

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 female)
#2) BREAST CANCER (Breast cancer female)

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

18. THERAPY DATES(from/to)
#1) 18-JUL-2025 / 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	Indication	Breast cancer (Breast cancer)
Unknown	Indication	Breast cancer female (Breast cancer female)

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-202508CAM000584CR
Case References: CR-AstraZeneca-CH-00923514A

24b. MFR CONTROL NO.
202508CAM000584CR

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

NAME AND ADDRESS WITHHELD.

24c. DATE RECEIVED BY MANUFACTURER
03-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: 202508CAM000584CR

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 urticaria (preferred term: Urticaria), generalised rash (preferred term: Rash) and blisters (preferred term: Blister).

It is unknown if any action was taken with Faslodex.

The outcome of the events of blisters, generalised rash and urticaria was unknown.

The events were considered serious (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: Blister is not a listed event in the core data sheet for fulvestrant. Underlying breast cancer could be confounding. Due to limited information on patient demographics, underlying comorbidities, past medical history and concomitant medications, suspect product action taken, circumstances leading to event, details of the event including onset date and outcome, risk factors, treatment details, clinical course, status of underlying comorbidities, detailed etiological, diagnostic workup as clinical examination, complete blood workup, the evaluation did not find evidence to suggest a causal relationship between event and suspect drug.