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		43 Years	Female	Unk	17	JUL	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
Patient presents Dizziness [Dizziness]	ZOLADEX	No	No	Related	Related
Patient presents Dizziness [Dizziness]	SafeSystem Pre-filled Applicator Syringe	No	No	Related	Related
Patient presents Abdominal pain [Abdominal pain]	ZOLADEX	No	No	Related	Related
Patient presents Abdominal pain [Abdominal pain]	SafeSystem Pre-filled Applicator Syringe	No	No	Related	Related
Patient presents want to vomit [Nausea]	ZOLADEX	No	No	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) ZOLADEX (GOSERELIN ACETATE) Depot injection
#2) SafeSystem Pre-filled Applicator Syringe (SafeSystem Pre-filled Applicator Syringe) Unknown {Lot # Unknown}

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

15. DAILY DOSE(S)
#1) 10.8 milligram, every 3 month
#2)

16. ROUTE(S) OF ADMINISTRATION
#1) Subcutaneous 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) Ongoing
#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 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-202412CAM018113CR
Study ID: PSP-23269
Case References: CR-AstraZeneca-CH-00772760A

24b. MFR CONTROL NO.
202412CAM018113CR

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

NAME AND ADDRESS WITHHELD.

24c. DATE RECEIVED BY MANUFACTURER
18-JUL-2025

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

DATE OF THIS REPORT
23-JUL-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

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
Patient presents want to vomit [Nausea]	SafeSystem Pre-filled Applicator Syringe	No	No	Related	Related
Patient presents "a feeling as if he were going to break down" [Feeling abnormal]	ZOLADEX	No	No	Related	Related
Patient presents "a feeling as if he were going to break down" [Feeling abnormal]	SafeSystem Pre-filled Applicator Syringe	No	No	Related	Related
Application site pain [Application site pain]	ZOLADEX	No	Yes	Not Applicable	Related
Application site pain [Application site pain]	SafeSystem Pre-filled Applicator Syringe	No	No	Not Applicable	Related
application site “feel swollen” [Application site oedema]	ZOLADEX	No	Yes	Not Applicable	Related
application site “feel swollen” [Application site oedema]	SafeSystem Pre-filled Applicator Syringe	No	No	Not Applicable	Related
feel warm at the application site [Application site warmth]	ZOLADEX	No	Yes	Unknown	Related
feel warm at the application site [Application site warmth]	SafeSystem Pre-filled Applicator Syringe	No	No	Not Applicable	Related
Patient presents purple, almost black at the treatment application site [Application site discolouration]	ZOLADEX	No	Yes	Not Applicable	Related
Patient presents purple, almost black at the treatment application site [Application site discolouration]	SafeSystem Pre-filled Applicator Syringe	No	No	Not Applicable	Related
Patient feels hard at treatment application site [Application site hypertrophy]	ZOLADEX	No	No	Not Applicable	Related
Patient feels hard at treatment application site [Application site hypertrophy]	SafeSystem Pre-filled Applicator Syringe	No	No	Not Applicable	Related

Case Description: A solicited report has been received from a consumer in Patient Support Program. The report concerns a female adult patient born in 1982 (age 43 years).

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Zoladex (goserelin acetate) 10.8 milligram, Subcutaneous use, on an unknown date for breast cancer.

It is unknown who administered Zoladex to the patient.

On 17-JUL-25, the patient experienced patient presents purple, almost black at the treatment application site (preferred term: Application site discolouration), feel warm at the application site (preferred term: Application site warmth), application site “feel swollen” (preferred term: Application site oedema), application site pain (preferred term: Application site pain) and patient feels hard at treatment application site (preferred term: Application site hypertrophy). On an unknown date, the patient experienced patient presents dizziness (preferred term: Dizziness), patient presents "a feeling as if he were going to break down" (preferred term: Feeling abnormal), patient presents want to vomit (preferred term: Nausea) and patient presents abdominal pain (preferred term: Abdominal pain).

The dose of Zoladex (goserelin acetate) was not changed.

The patient recovered from the event(s) patient presents abdominal pain, patient presents "a feeling as if he were going to break down", patient presents dizziness and patient presents want to vomit on an unspecified date. At the time of reporting, the event application site pain, application site “feel swollen”, feel warm at the application site, patient feels hard at treatment application site and patient presents purple, almost black at the treatment application site was improving.

The events were considered non-serious.

The reporter did not assess causality for application site pain, application site “feel swollen”, feel warm at the application site, patient feels hard at treatment application site and patient presents purple, almost black at the treatment application site.The reporter considered that there was a reasonable possibility of a causal relationship between Safesystem Pre-Filled Applicator Syringe and the following event(s): patient presents abdominal pain, patient presents "a feeling as if he were going to break down", patient presents dizziness and patient presents want to vomit. The reporter considered that there was a reasonable possibility of a causal relationship between Zoladex and the following event(s): patient presents abdominal pain, patient presents "a feeling as if he were going to break down", patient presents dizziness and patient presents want to vomit.
The company physician considered that there was a reasonable possibility of a causal relationship between Safesystem Pre-Filled Applicator Syringe and the following event(s): application site pain, application site “feel swollen”, feel warm at the application site, patient feels hard at treatment application site, patient presents abdominal pain, patient presents "a feeling as if he were going to break down", patient presents dizziness, patient presents purple, almost black at the treatment application site and patient presents want to vomit. The company physician considered that there was a reasonable possibility of a causal relationship between Zoladex and the following event(s): application site pain, application site “feel swollen”, feel warm at the application site, patient feels hard at treatment application site, patient presents abdominal pain, patient presents "a feeling as if he were going to break down", patient presents dizziness, patient presents purple, almost black at the treatment application site and patient presents want to vomit.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

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

Summary of follow-up information received on 18-JUL-2025 from Consumer via Patient Support Program: New event added as Application site pain, Application site edema, Application site burning, Application site hematomata, Application site hypertrophy. Causality added. Narrative updated