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		74 Years	Male	Unk	17	AUG	2023

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
sexual appetite is gone [Loss of libido]	ZOLADEX	No	Yes	Related	Related
sexual appetite is gone [Loss of libido]	SafeSystem Pre-filled Applicator Syringe	No	No	Not Applicable	Not Related
suffers from hot flashes [Hot flush]	ZOLADEX	No	Yes	Related	Related
suffers from hot flashes [Hot flush]	SafeSystem Pre-filled Applicator Syringe	No	No	Not Applicable	Not Related
Stress [Stress]	ZOLADEX	No	No	Unknown	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 {Lot # Unknown}
#2) SafeSystem Pre-filled Applicator Syringe (SafeSystem Pre-filled Applicator Syringe) Unknown

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

15. DAILY DOSE(S)
#1) 10.8 milligram, Every 3 months
#2)

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

17. INDICATION(S) FOR USE
#1) Unknown
#2) Unknown

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

18. THERAPY DATES(from/to)
#1) 17-AUG-2023 / 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)
#1) Radiotherapy ; Unknown

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	Prostate cancer (Prostate 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-202505CAM019200CR
Study ID: PSP-23269
Case References: CR-AstraZeneca-CH-00876233A

24b. MFR CONTROL NO.
202505CAM019200CR

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

NAME AND ADDRESS WITHHELD.

24c. DATE RECEIVED BY MANUFACTURER
22-MAY-2025

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

DATE OF THIS REPORT
26-MAY-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 202505CAM019200CR

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
Stress [Stress]	SafeSystem Pre-filled Applicator Syringe	No	No	Not Applicable	Not Related
Constipation [Constipation]	ZOLADEX	No	No	Unknown	Related
Constipation [Constipation]	SafeSystem Pre-filled Applicator Syringe	No	No	Not Applicable	Not Related
pain in the application area [Injection site pain]	ZOLADEX	No	Yes	Related	Not Related
pain in the application area [Injection site pain]	SafeSystem Pre-filled Applicator Syringe	No	No	Not Applicable	Related
Prostitis (rectal bleeding) [Prostatitis]	ZOLADEX	No	No	Not Related	Not Related
Prostitis (rectal bleeding) [Prostatitis]	SafeSystem Pre-filled Applicator Syringe	No	No	Not Applicable	Not Related

Case Description: A solicited report has been received from a non-health professional in Patient Support Program. The report concerns a male elderly patient born in 1949 (age 74 years).

No medical history was reported.

Concomitant medication included Radiotherapy for prostate cancer.

The patient started treatment with Zoladex (goserelin acetate) (batch number(s) Unknown) 10.8 milligram every 3 months, Subcutaneous use, on 17-AUG-2023.

On 17-AUG-23, the patient experienced sexual appetite is gone (preferred term: Loss of libido), pain in the application area (preferred term: Injection site pain) and suffers from hot flashes (preferred term: Hot flush). On an unknown date, the patient experienced stress (preferred term: Stress), prostitis (rectal bleeding) (preferred term: Prostatitis) and constipation (preferred term: Constipation).

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

At the time of reporting, the event constipation, prostitis (rectal bleeding), sexual appetite is gone, stress and suffers from hot flashes was ongoing. The outcome of the event(s) of pain in the application area was unknown.

The events were considered non-serious.

The reporter did not assess causality for constipation, pain in the application area, prostitis (rectal bleeding), sexual appetite is gone, stress and suffers from hot flashes.The reporter considered that there was a reasonable possibility of a causal relationship between Zoladex and the following event(s): pain in the application area, sexual appetite is gone and suffers from hot flashes. The reporter did not consider that there was a reasonable possibility of a causal relationship between Zoladex and the following event(s): prostitis (rectal bleeding).
The company physician did not consider that there was a reasonable possibility of a causal relationship between Safesystem Pre-Filled Applicator Syringe and the following event(s): constipation, prostitis (rectal bleeding), sexual appetite is gone, stress and suffers from hot flashes. The company physician did not consider that there was a reasonable possibility of a causal relationship between Zoladex and the following event(s): pain in the application area and prostitis (rectal bleeding). 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): pain in the application area. The company physician considered that there was a reasonable possibility of a causal relationship between Zoladex and the following event(s): constipation, sexual appetite is gone, stress and suffers from hot flashes.

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