

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY COSTA RICA	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION <input type="checkbox"/> PATIENT DIED <input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION <input type="checkbox"/> INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY <input type="checkbox"/> LIFE THREATENING <input type="checkbox"/> CONGENITAL ANOMALY <input type="checkbox"/> OTHER
		Day	Month	Year				Day	Month	Year	
			PRIVACY		Unk	Female	Unk		MAY	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
Patient indicates that his head went up pressure [Head discomfort]	GOSERELIN ACETATE	No	No	Related	Related
Patient indicates that his head went up pressure [Head discomfort]	SafeSystem Pre-filled Applicator Syringe	No	No	Related	Related
Patient indicates that his head went up pressure [Head discomfort]	ARIMIDEX	No	Yes	Not Related	Not Related
Patient presents pain in joints [Arthralgia]	GOSERELIN ACETATE	No	Yes	Related	Related
Patient presents pain in joints [Arthralgia]	SafeSystem Pre-filled Applicator Syringe	No	No	Related	Related

(Continued on Additional Information Page)

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1) GOSERELIN ACETATE (GOSERELIN ACETATE) Solution for injection in pre-filled syringe {Lot # unknown} #2) SafeSystem Pre-filled Applicator Syringe (SafeSystem Pre-filled) (Continued on Additional Information Page)		20. DID REACTION ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
15. DAILY DOSE(S) #1) 3.6 milligram, qmonth #2)	16. ROUTE(S) OF ADMINISTRATION #1) Subcutaneous use #2) Unknown	
17. INDICATION(S) FOR USE #1) Ovarian cancer (Ovarian cancer) #2) ovarian cancer (Ovarian cancer)		21. DID REACTION REAPPEAR AFTER REINTRODUCTION? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> 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 Unknown to Ongoing Unknown to Ongoing	Type of History / Notes Indication Indication	Description Breast cancer female (Breast cancer female) Breast cancer (Breast cancer)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER AstraZeneca Serban Ghiorghe 1 Medimmune Way Gaithersburg, Maryland 20878 UNITED STATES Phone: +1 301-398-0000		26. REMARKS World Wide #: CR-ASTRAZENECA-202410CAM028274CR Study ID: PSP-23269 Case References: CR-AstraZeneca-CH-00738979AM
	24b. MFR CONTROL NO. 202410CAM028274CR	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 29-APR-2025	24d. REPORT SOURCE <input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL <input type="checkbox"/> OTHER:	NAME AND ADDRESS WITHHELD.
DATE OF THIS REPORT 05-MAY-2025	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> FOLLOWUP: 2	

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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 pain in joints [Arthralgia]	ARIMIDEX	No	Yes	Not Related	Not Related
Patient presents discomfort in joints [Arthropathy]	GOSERELIN ACETATE	No	No	Related	Related
Patient presents discomfort in joints [Arthropathy]	SafeSystem Pre-filled Applicator Syringe	No	No	Related	Related
Patient presents discomfort in joints [Arthropathy]	ARIMIDEX	No	No	Not Related	Not Related
Patient presents bone pain [Bone pain]	GOSERELIN ACETATE	No	No	Related	Related
Patient presents bone pain [Bone pain]	SafeSystem Pre-filled Applicator Syringe	No	No	Related	Related
Patient presents bone pain [Bone pain]	ARIMIDEX	No	Yes	Not Related	Not Related
Patient presents discomfort in bones [Bone disorder]	GOSERELIN ACETATE	No	No	Related	Related
Patient presents discomfort in bones [Bone disorder]	SafeSystem Pre-filled Applicator Syringe	No	No	Related	Related
Patient presents discomfort in bones [Bone disorder]	ARIMIDEX	No	No	Not Related	Not Related
Patient indicates that "it's hard walk." [Gait disturbance]	GOSERELIN ACETATE	No	No	Related	Related
Patient indicates that "it's hard walk." [Gait disturbance]	SafeSystem Pre-filled Applicator Syringe	No	No	Related	Related
Patient indicates that "it's hard walk." [Gait disturbance]	ARIMIDEX	No	No	Not Related	Not Related
Patient indicates that "it gives him a lot weeping" [Crying]	GOSERELIN ACETATE	No	No	Related	Related
Patient indicates that "it gives him a lot weeping" [Crying]	SafeSystem Pre-filled Applicator Syringe	No	No	Related	Related
Patient indicates that "it gives him a lot weeping" [Crying]	ARIMIDEX	No	No	Not Related	Not Related
Patient indicates that "i'm like depressive." [Depression]	GOSERELIN ACETATE	No	No	Related	Related
Patient indicates that "i'm like depressive." [Depression]	SafeSystem Pre-filled Applicator Syringe	No	No	Related	Related
Patient indicates that "i'm like depressive." [Depression]	ARIMIDEX	No	Yes	Not Related	Not Related
Patient indicates that it's very sentimental. [Emotional disorder]	GOSERELIN ACETATE	No	No	Related	Related
Patient indicates that it's very sentimental. [Emotional disorder]	SafeSystem Pre-filled Applicator Syringe	No	No	Related	Related
Patient indicates that it's very sentimental. [Emotional disorder]	ARIMIDEX	No	No	Not Related	Not Related

Case Description: A solicited report has been received from a consumer in Patient Support Program. The report concerns a female patient born in 1974.

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Arimidex (anastrozole) (batch number(s) Unknown) 1 milligram qd, Oral use, on an unknown date and with Goserelin Acetate (goserelin acetate) (batch number(s) unknown) 3.6 milligram qmonth, Subcutaneous use, on an unknown date for ovarian cancer.

It is unknown who administered Goserelin Acetate to the patient.

During 15-MAY-23, the patient experienced patient presents discomfort in joints (preferred term: Arthropathy) and patient presents discomfort in bones (preferred term: Bone disorder). On an unknown date, the patient experienced patient indicates that his head went up pressure (preferred term: Head discomfort), patient indicates that it's very sentimental. (preferred term: Emotional disorder), patient indicates that "i'm like depressive." (preferred term: Depression), patient indicates that "it gives him a lot weeping" (preferred term: Crying), patient indicates that "it's hard walk." (preferred term: Gait disturbance), patient presents bone pain (preferred term: Bone pain) and patient presents pain in joints (preferred term: Arthralgia).

The dose of Arimidex (anastrozole) was not changed.

At the time of reporting, the event patient indicates that "i'm like depressive.", patient indicates that "it gives him a lot weeping", patient indicates that "it's hard walk.", patient indicates that his head went up pressure, patient presents bone pain, patient presents discomfort in bones, patient presents discomfort in joints and patient presents pain in joints was ongoing. The outcome of the event(s) of patient indicates that it's very sentimental. was unknown.

The events were considered non-serious.

The reporter did not consider that there was a reasonable possibility of a causal relationship between Arimidex and the following event (s): patient indicates that "i'm like depressive.", patient indicates that "it gives him a lot weeping", patient indicates that "it's hard walk.", patient indicates that his head went up pressure, patient indicates that it's very sentimental., patient presents bone pain, patient presents discomfort in bones, patient presents discomfort in joints and patient presents pain in joints. The reporter considered that there was a reasonable possibility of a causal relationship between Goserelin Acetate and the following event(s): patient indicates that "i'm like depressive.", patient indicates that "it gives him a lot weeping", patient indicates that "it's hard walk.", patient indicates that his head went up pressure, patient indicates that it's very sentimental., patient presents bone pain, patient presents discomfort in bones,

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

patient presents discomfort in joints and patient presents pain in joints. 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 indicates that "i'm like depressive.", patient indicates that "it gives him a lot weeping", patient indicates that "it's hard walk.", patient indicates that his head went up pressure, patient indicates that it's very sentimental., patient presents bone pain, patient presents discomfort in bones, patient presents discomfort in joints and patient presents pain in joints.

The company physician did not consider that there was a reasonable possibility of a causal relationship between Arimidex and the following event(s): patient indicates that "i'm like depressive.", patient indicates that "it gives him a lot weeping", patient indicates that "it's hard walk.", patient indicates that his head went up pressure, patient indicates that it's very sentimental., patient presents bone pain, patient presents discomfort in bones, patient presents discomfort in joints and patient presents pain in joints. The company physician considered that there was a reasonable possibility of a causal relationship between Goserelin Acetate and the following event(s): patient indicates that "i'm like depressive.", patient indicates that "it gives him a lot weeping", patient indicates that "it's hard walk.", patient indicates that his head went up pressure, patient indicates that it's very sentimental., patient presents bone pain, patient presents discomfort in bones, patient presents discomfort in joints and patient presents pain in joints. 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): patient indicates that "i'm like depressive.", patient indicates that "it gives him a lot weeping", patient indicates that "it's hard walk.", patient indicates that his head went up pressure, patient indicates that it's very sentimental., patient presents bone pain, patient presents discomfort in bones, patient presents discomfort in joints and patient presents pain in joints.

Device Information:
Combination Product Report: Yes
Product As Reported: Goserelin Acetate
Brand Name: GOSERELIN ACETATE
Product Role: Suspect
Manufacturer Name: ASTRAZENECA
Labeled for single use: No

Corrected report on 02-Jan-2025: Conditional Listedness for event Bone pain corrected from listed to unlisted. Event recoded. Device constituent added. Narrative amended.

Summary of follow up information received by AstraZeneca on 29-APR-2025 from Consumer via solicited source: Study ID PSP-23269 updated. Action taken updated from no change to withdrawn. The Other relevant history was updated. Narrative updated.

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#2) SafeSystem Pre-filled Applicator Syringe (SafeSystem Pre-filled Applicator Syringe) Unknown; Regimen #1	; Unknown	ovarian cancer (Ovarian cancer)	Unknown; Unknown
#3) ARIMIDEX (ANASTROZOLE) Film-coated tablet {Lot # Unknown}; Regimen #1	1 milligram, qd; Oral use	(Not Coded)	Ongoing; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Indication	Ovarian cancer (Ovarian cancer);
Unknown	Procedure	Hysterectomy NOS (Hysterectomy);