SUSPECT ADVERSE REACTION REPORT

SV-Tolmar-TLM-2025-05369

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	4-6 REACTION ONSET		
		Day	Month	Year	Years		Day	Month	Year
ATB	EL Cont..	31	May	1952	73	Male	31	Jul	2025

7+13 DESCRIBE REACTION(S) (including relevant tests/lab data)

1) Nauseas/nausea (Nausea (10028813), Nausea (10028813))
(31/Jul/2025 -) - Recovered/Resolved

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENCE OR SIGNIFICANT DISABILITY/INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II. SUSPECT DRUG(S)INFORMATION

14. SUSPECT DRUG(S)(include generic name)

1) Eligard® (Leuprolide acetate, Leuprolide acetate) (Suspect) (Injection)(UNK; UNK; 15274CUY) Cont..

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

15. DAILY DOSE(S)

1) (22.5 milligram(s), 1 in 3 Month)

16. ROUTE(S) OF ADMINISTRATION

1) Subcutaneous

21. DID EVENT REAPPEAR AFTER REINTRODUCTION ☐ YES ☐ NO ☑ NA

(NA : Not Applicable)

17. INDICATION(S) FOR USE

1) Prostate cancer [10060862 - Prostate cancer]

18. THERAPY DATE(S) (from/to)	19. THERAPY DURATION
1) (01/Aug/2024 -)	

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

No concomitants used/reported

23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

1) PROSTATE CANCER (10060862, Prostate cancer) (Continuing: Yes)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER

Name : Tolmar, Inc
701 Centre Avenue
Fort Collins, CO, 80526, UNITED STATES OF AMERICA
Anjan.Chatterjee@tolmar.comand+1--9702124900

Study Information
Study Name: NA
EudraCT Number:
Protocol No.: NA
Center No.:
Subject Id :

24.REPORT NULLIFIED	24b. MFR CONTROL NO.
☐ YES ☐ NO	SV-Tolmar-TLM-2025-05369
24c. DATE RECEIVED BY MANUFACTURER: 31/Jul/2025	24d. REPORT SOURCE: ☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT: 05/Aug/2025	25a. REPORT TYPE: ☑ INITIAL ☐ FOLLOWUP

= Continuation attached sheet(s)..

Continuation Sheet for CIOMS report

1a. COUNTRY

EL SALVADOR

7+13 DESCRIBE REACTION(S) (including relevant tests/lab data) (Continuation...)

Event Description :

This study report from El Salvador was received by Adium via “ASOFARMA A TU LADO" Patient Support Program (reference number: SV-ADIUM-SV-0018-20250731 (0)) on 31-Jul-2025 from a consumer (non-healthcare professional) regarding an elderly 73-year-old male patient who experienced a non-serious event of ‘‘Nauseas/nausea" (nausea) during Eligard (Leuprolide acetate) 22.5 mg therapy for prostate cancer. The needle component of the constituent device was not identified in the report. The report was sent to Tolmar on 01-Aug-2025.

The patient's medical history was unknown and current condition included prostate cancer.

Concomitant medications were not reported.

On 01-Aug-2024, the patient began receiving Eligard 22.5 mg, every 3 months, via subcutaneous route for prostate cancer (Lot numbers: UNK; UNK; 15274CUY and Expiration dates: UNK; UNK; Aug-2026).

On 31-Jul-2025, the patient experienced moderate nausea. No further information was provided.

Correction treatment included Dramavol (dimenhydrinate).

Action taken with Eligard in response to the event was unknown. De-challenge and re-challenge were not applicable.

The outcome of nausea was recovered.

The reporter assessed the seriousness of nausea as non-serious.

The reporter assessed the causality of nausea in relationship to Eligard and Eligard unspecified device as related.

No further information is expected as consent to be contacted was not provided.

Listedness:
Nausea>Eligard>listed as per CCDS>07-Nov-2024
Nausea>Eligard>listed as per USPI>Feb-2025
Nausea>Eligard unspecified device>listed as per USPI>Feb-2025
Nausea>Eligard>listed as per Canadian monograph>O2-Apr-2025

Company Remarks (Sender's Comments) :

Evaluator comment (Tolmar): This case is regarding an elderly 73-year-old male patient who experienced nausea (nauseas) during Eligard (Leuprolide acetate) 22.5 mg therapy for prostate cancer. Tolmar assessed the event as non-serious since it does not meet the ICH seriousness criteria and is not an IME event. The event nausea was considered as related as the contributory role of suspect drug Eligard cannot be ruled out considering known pharmacological profile of the drug. Nausea was assessed as not related to the device component of Eligard.

14.SUSPECT DRUG(S) (Continuation...)

Product-Reaction Level

1) Drug	:	Eligard® (Leuprolide acetate)
Active Substance	:	1) Leuprolide acetate
Drug Characterization	:	Suspect
Form of Admin	:	1) Injection
Lot Number	:	1) UNK; UNK; 15274CUY
Daily Dose	:	(22.5 milligram(s), 1 in 3 Month)
Route of Admin	:	1) Subcutaneous
Indications	:	1) Prostate cancer [10060862 - Prostate cancer]
Therapy Dates	:	1) From : 01/Aug/2024 To :Unknown
Action(s) Taken With Drug	:	Unknown

Causality

1) Nauseas/nausea (Nausea - 10028813, Nausea - 10028813)

Causality as per reporter	:	Related
Causality as per Mfr	:	Related

Continuation Sheet for CIOMS report

DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) Nauseas/nausea
CORE Labeled

2) Drug : Eligard® Unspecified Device (Leuprolide acetate)
Active Substance : 1) Leuprolide acetate
Drug Characterization : Suspect
Form of Admin : 1) Injection
Lot Number : 1) UNK; UNK; 15274CUY
Indications : 1) Prostate cancer [10060862 - Prostate cancer]
Action(s) Taken With Drug : Not applicable

Causality

1) Nauseas/nausea (Nausea - 10028813, Nausea - 10028813)
Causality as per reporter : Related
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) Nauseas/nausea
CORE

15. DAILY DOSE(S) (Continuation...)

Dosage Text :

Drug 1 :Eligard®

1) Expiration dates: UNK; UNK; Aug-2026

Drug 2 :Eligard® Unspecified Device

1) Expiration dates: UNK; UNK; Aug-2026