SUSPECT ADVERSE REACTION REPORT

SV-Tolmar-TLM-2025-04727

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year	Years		Day	Month	Year	
MFFS	EL Cont..	19	Dec	1972	52	Male	01	Apr	2025	

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

1) Patient reports feeling slightly dizzy (Dizziness (10013573), Dizziness (10013573))
(/Apr/2025 -) - Unknown
2) patient being treated with the drug Eligard 22.5 mg lyophilized for injectable suspension at a dose of 22.5 mg per day every 3 months (Off label dosing frequency (10076395), Off label use (10053762))
(01/Apr/2025 -) - Unknown

- ☐ 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)(Unknown)(15274Cuy; Unk; Unk) Cont..

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

15. DAILY DOSE(S)

(22.5 milligram(s))

(22.5 milligram(s)) Cont..

16. ROUTE(S) OF ADMINISTRATION

1) Subcutaneous
2) Subcutaneous Cont..

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

(NA : Not Applicable)

17. INDICATION(S) FOR USE

1) prostate cancer [10060862 - Prostate cancer] Cont..

18. THERAPY DATE(S) (from/to)	19. THERAPY DURATION
1) (//2025 -)	

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-2025-04727
24c. DATE RECEIVED BY MANUFACTURER	24d. REPORT SOURCE
15/Jul/2025	☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT	25a. REPORT TYPE
18/Jul/2025	☑ 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 Patient Support Programme (Reference number: SV-ADIUM-SV-0013-20250715) on 15-Jul-2025 from a reporter (consumer or non-healthcare professional) regarding an adult, 52-year-old male patient who experienced non-serious events of ‘‘Patient reports feeling slightly dizzy" (dizziness) and "patient being treated with the drug Eligard 22.5 mg lyophilized for injectable suspension at a dose of 22.5 mg per day every 3 months" (off label use) 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 16-Jul-2025. Bicalutamide was considered as co-suspect at 50 mg dosage for prostate cancer.

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

Concomitant medication was unknown.

On 01-Apr-2025, the patient began receiving Eligard 22.5 mg per day every 3 months, via subcutaneous route, for prostate cancer (Lot numbers:15274Cuy; Unk; Unk and Expiration dates were not provided).

On an unknown date in 2025, the patient received the latest dose of Eligard 22.5 mg per day every 3 months, via subcutaneous route, for prostate cancer (Lot numbers and Expiration dates were not provided) and patient was feeling dizzy and felt stronger than the Apr-2025 application. No further details were provided.

Corrective treatment was unknown.

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

The outcome of dizziness and off label use was unknown.

The reporter did not assess the seriousness of dizziness and off label use.

The reporter did not provide the causality of off label use in relationship to Eligard and Eligard unspecified device.

The reporter provided the causality of dizziness in relationship to Eligard and Eligard unspecified device as related.

No further query was raised.

Note: As there was a discrepancy in the dates of the event dizziness, we are conservatively taking the partial date for this event as 2025.

Listedness:

Dizziness>Eligard>Unlisted as per CCDS>07-Nov-2024
Dizziness>Eligard>Unlisted as per USPI>Feb-2025
Dizziness>Eligard Terumo Needle Pre-connected Syringe>Unlisted as per USPI>Feb-2025
Dizziness>Eligard>Unlisted as per Canadian monograph>02-Apr-2025

Off label use>Eligard>Unlisted as per CCDS>07-Nov-2024
Off label use>Eligard>Unlisted as per USPI>Feb-2025
Off label use>Eligard Terumo Needle Pre-connected Syringe>Unlisted as per USPI>Feb-2025
Off label use>Eligard>Unlisted as per Canadian monograph>02-Apr-2025

Company Remarks (Sender's Comments) :

Evaluators comments : As per company conventions, the events Dizziness, Off label use are considered with not applicable causality by default. The events are unlisted/unexpected with reference to the current CCDS/SmPC and as per company conventions. All the events are non-serious. The benefit-risk profile of Eligard (Drug and device) is not adversely affected by this report.

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

Product-Reaction Level

1) Drug	:	Eligard® (Leuprolide acetate)
Active Substance	:	1) Leuprolide acetate

Continuation Sheet for CIOMS report

Drug Characterization : Suspect
Form of Admin : 1) Injection
2) Injection
Lot Number : 1) Unknown
2) 15274Cuy; Unk; Unk
Daily Dose : (22.5 milligram(s))
(22.5 milligram(s))
Route of Admin : 1) Subcutaneous
2) Subcutaneous
Indications : 1) prostate cancer [10060862 - Prostate cancer]
Therapy Dates : 1) From : //2025 To :Unknown
2) From : 01/Apr/2025 To :Unknown
Action(s) Taken With Drug : Unknown

Causality

1) Patient reports feeling slightly dizzy (Dizziness - 10013573, Dizziness - 10013573)
Causality as per reporter : Related
Causality as per Mfr : Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

2) patient being treated with the drug Eligard 22.5 mg lyophilized for injectable suspension at a dose of 22.5 mg per day every 3 months (Off label dosing frequency - 10076395, Off label use - 10053762)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) Patient reports feeling slightly dizzy
CORE Labeled
2) patient being treated with the drug Eligard 22.5 mg lyophilized for injectable suspension at a dose of 22.5 mg per day every 3 months
CORE UnLabeled

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

Causality

1) Patient reports feeling slightly dizzy (Dizziness - 10013573, Dizziness - 10013573)
Causality as per reporter : Related
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

2) patient being treated with the drug Eligard 22.5 mg lyophilized for injectable suspension at a dose of 22.5 mg per day every 3 months (Off label dosing frequency - 10076395, Off label use - 10053762)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) Patient reports feeling slightly dizzy
CORE
2) patient being treated with the drug Eligard 22.5 mg lyophilized for injectable suspension at a dose of 22.5 mg per day every 3 months
CORE

3) Drug : BICALUTAMIDE
Active Substance : 1) BICALUTAMIDE
Drug Characterization : Suspect
Lot Number : 1) Unknown
Daily Dose : (50 milligram(s), 1 in 1 Day)
Route of Admin : 1) Oral

Continuation Sheet for CIOMS report

Indications : 1) prostate cancer [10060862 - Prostate cancer]
Action(s) Taken With Drug : Unknown

Causality

1) Patient reports feeling slightly dizzy (Dizziness - 10013573, Dizziness - 10013573)
Causality as per reporter : Not Reported

2) patient being treated with the drug Eligard 22.5 mg lyophilized for injectable suspension at a dose of 22.5 mg per day every 3 months (Off label dosing frequency - 10076395, Off label use - 10053762)
Causality as per reporter : Not Reported

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

Dosage Text :

Drug 1 :Eligard®

1) 22.5 mg per day every 3 months

2) 22.5 mg per day every 3 months