SUSPECT ADVERSE REACTION REPORT

SV-Tolmar-TLM-2025-05368

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE Years	3. SEX	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year			Day	Month	Year	
EVMM	EL Cont..	16	Mar	1971	54	Male	31	Jul	2025	

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

1) Dizziness (Dizziness (10013573), Dizziness (10013573))
(31/Jul/2025 -) - Recovering/Resolving

- ☐ 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)(15274CUY; Unk; Unk) 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) (/Jul/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) (//2025 -) (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-2025-05368
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 an electronic form through the Jazz Safety tool of the Patient Support Program “ASOFARMA A TU LADO” (Reference number: SV-ADIUM-SV-0019-20250731) on 31-Jul-2025 from a reporter (consumer or non-healthcare professional) regarding an adult, 54-year-old male patient who experienced a non-serious event of ‘‘Dizziness'' (Dizziness) 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 medication was unknown.

On an unknown date in Jul-2025, the patient began receiving Eligard 22.5 mg every 3 months, via subcutaneous route, for prostate cancer (Lot numbers: 15274CUY; Unk; Unk and Expiration dates: Aug-2026).

On 31-Jul-2025, the patient reported feeling moderate dizziness. No further details were provided.

Corrective treatment was unknown.

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

The outcome of dizziness was recovering.

The reporter did not assess the seriousness of dizziness.

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

No further query was raised.

Listedness:
Dizziness>Eligard>listed as per CCDS>07-Nov-2024
Dizziness>Eligard>listed as per USPI>Feb-2025
Dizziness>Eligard unspecified device>listed as per USPI>Feb-2025
Dizziness>Eligard>listed as per Canadian monograph>02-Apr-2025

Company Remarks (Sender's Comments) :

Evaluator comment (Tolmar): This case is regarding an adult 54-year-old male patient who experienced dizziness (dizziness) 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 dizziness was considered as related as the contributory role of suspect drug Eligard cannot be ruled out considering known pharmacological profile of the drug and close temporal association with Eligard administration. Dizziness 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) 15274CUY; Unk; Unk
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 : /Jul/2025 To :Unknown
Action(s) Taken With Drug	:	Unknown

Causality

1) Dizziness (Dizziness - 10013573, Dizziness - 10013573)

Continuation Sheet for CIOMS report

Causality as per reporter	: Related
Causality as per Mfr	: Related
DeChallenge	: Not applicable
ReChallenge	: Not Applicable

Labeling :

1) Dizziness
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) 15274CUY; Unk; Unk
Indications	: 1) Prostate cancer [10060862 - Prostate cancer]
Action(s) Taken With Drug	: Not applicable

Causality

1) Dizziness (Dizziness - 10013573, Dizziness - 10013573)

Causality as per reporter	: Related
Causality as per Mfr	: Not Related
DeChallenge	: Not applicable
ReChallenge	: Not Applicable

Labeling :

1) Dizziness
CORE