SUSPECT ADVERSE REACTION REPORT

SV-Tolmar-TLM-2025-04404

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	
JACC	EL Cont..	12	Jun	1957	68	Male			2024	

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

1) Medication suspension (Therapy cessation (10065154), Therapy cessation (10065154)) (//2024 -) - Unknown

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)(Unknown)(Unknown) Cont..

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

15. DAILY DOSE(S)

1) (45 milligram(s), 1 in 6 Month)

2) (45 milligram(s), 1 in 6 Month)

16. ROUTE(S) OF ADMINISTRATION

1) Subcutaneous

2) 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) (//2024 - --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) (/Apr/2023 - //2024) (Continuing: No)

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-2025-04404
24c. DATE RECEIVED BY MANUFACTURER: 03/Jul/2025	24d. REPORT SOURCE: ☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT: 08/Jul/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 Invalid case report from EL SALVADOR was received by Adium via Patient Support Program (reference number: SV-ADIUM-SV-0010-20250703) on 03-Jul-2025 from a consumer (non-healthcare professional) regarding an elderly 68-year-old male patient who had non-serious event of ‘‘medication suspension" (Therapy cessation) during Eligard (leuprolide acetate) 45 mg therapy for prostate cancer. The report was sent to Tolmar on 04-Jul-2025.

This report was assessed as invalid as no adverse event was reported. The reported term ‘‘medication suspension" (Therapy cessation) was not considered as an adverse event as per case processing convention.

Listedness
Therapy cessation >Eligard® >unlisted as per CCDS Eligard®> 7-Nov-2024
Therapy cessation> Eligard® >unlisted as per Canadian Monograph Eligard®> 2-Apr-2025
Therapy cessation> Eligard®>unlisted as per USPI Eligard®>Feb-2025
Therapy cessation> Eligard® Unspecified Device>unlisted as per USPI Eligard®>Feb-2025

Company Remarks (Sender's Comments) :

Evaluator comment(Tolmar): This report was assessed as invalid as no adverse event was reported. The reported term ‘‘medication suspension" (Therapy cessation) was not considered as an adverse event as per case processing convention.

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 2) Injection
Lot Number	:	1) Unknown 2) Unknown
Daily Dose	:	(45 milligram(s), 1 in 6 Month) (45 milligram(s), 1 in 6 Month)
Route of Admin	:	1) Subcutaneous 2) Subcutaneous
Indications	:	1) Prostate cancer [10060862 - Prostate cancer]
Therapy Dates	:	1) From : //2024 To :Not applicable 2) From : 25/Apr/2023 To :Not applicable
Action(s) Taken With Drug	:	Not applicable

Causality

1) Medication suspension (Therapy cessation - 10065154, Therapy cessation - 10065154)

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

Labeling :

1) Medication suspension
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
Route of Admin	:	1) Subcutaneous
Indications	:	1) Prostate cancer [10060862 - Prostate cancer]
Action(s) Taken With Drug	:	Not applicable

Continuation Sheet for CIOMS report

Causality

1) Medication suspension (Therapy cessation - 10065154, Therapy cessation - 10065154)

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

Labeling :

1) Medication suspension
CORE

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

Dosage Text :

Drug 1 :Eligard®

1) 45 mg

2) 45 mg