SUSPECT ADVERSE REACTION REPORT

PA-Tolmar-TLM-2025-00563

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE Years	3. SEX	4-6 REACTION ONSET		
		Day	Month	Year			Day	Month	Year
L-C	PANAMA	27	Aug	1947	77	Male	28	Mar	2025

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

1) Increased prostate antigen/prostate antigen laboratory test where it was increased to 70 (Prostatic specific antigen increased (10036975), Prostatic specific antigen increased (10036975))
(28/Mar/2025 -) - Not Recovered/Not Resolved/Ongoing

Cont..

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) (45 Milligram, Injection)(15276CUY; Unk; Unk)

Cont..

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

15. DAILY DOSE(S)

1) (45 milligram(s), 1 in 6 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) (24/Apr/2024 - Ongoing)	

III. CONCOMITANT DRUG(S) AND HISTORY

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

1)BICALUTAMIDE(BICALUTAMIDE)

Cont..

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
debbie.maierhofer@tolmar.comand+1-4129158447

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

24.REPORT NULLIFIED	24b. MFR CONTROL NO.
☐ YES ☐ NO	PA-Tolmar-TLM-2025-00563
24c. DATE RECEIVED BY MANUFACTURER	24d. REPORT SOURCE
14/Apr/2025	☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT	25a. REPORT TYPE
25/Apr/2025	☑ INITIAL ☐ FOLLOWUP

= Continuation attached sheet(s)..

Continuation Sheet for CIOMS report

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

Event Description :

This study report from Panama was received by Adium (reference number: PA-ADIUM-PA-0038-20250414) via an email from Patient Support Program on 14-Apr-2025 from a consumer (patient/non-healthcare professional) regarding an elderly 77-year-old male patient who experienced a serious (medically significant) event of ‘increased prostate antigen/prostate antigen laboratory test where it was increased to 70” (Prostatic specific antigen increased) during Eligard (leuprolide acetate) 45 milligram therapy for prostate cancer. The needle component of the constituent device was not identified in the report. The report was sent to Tolmar on 15-Apr-2025.

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

Concomitant medication included bicalutamide.

On 24-Apr-2024, the patient began receiving Eligard 45 mg lyophilized for injectable suspension, every 6 months via subcutaneous route for prostate cancer (Lot numbers: 15276CUY; Unk; Unk and Expiration dates: Aug-2026; Unk; Unk).

On an unknown date, the patient's PSA was 11.

On 28-Mar-2025, the patient underwent a prostate antigen laboratory test, which was increased to 70.

It was reported that 3 months after the application of the treatment, a prostatic antigen test would be performed to see if the values decreased, and if not, he would be referred to an oncologist. No further details were available.

Corrective treatment was unknown.

Relevant test results included:
On an unknown date: PSA: 11 (Ref. range: Not provided).
On 28-Mar-2025: PSA: 70 (Ref. range: Not provided).

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

The outcome of prostatic specific antigen increased was not resolved.

The reporter did not assess the seriousness of prostatic specific antigen increased.

The reporter did not provide the causality of prostatic specific antigen increased in relationship to Eligard and Eligard unspecified device.

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

Listedness
Prostate specific antigen increased >Eligard® >listed as per CCDS Eligard®> 7-Nov-2024
Prostate specific antigen increased> Eligard® >listed as per Canadian Monograph Eligard®> 2-Apr-2025
Prostate specific antigen increased> Eligard®>listed as per USPI Eligard®>Feb-2025
Prostate specific antigen increased> Eligard® Unspecified Device>listed as per USPI Eligard®>Feb-2025

Company Remarks (Sender's Comments) :

Evaluator comment (Tolmar): This case is regarding an elderly 77-year-old male patient who reported prostate specific antigen increased (increased prostate antigen/prostate antigen laboratory test where it was increased to 70) during Eligard(leuprolide acetate) 45mg therapy for prostate cancer. Tolmar assessed the reported event as serious since the value of PSA increased to 70 from 11 which is threefold increase from baseline value while on Eligard treatment as per company convention. The causality of event prostate specific antigen increased was assessed as not related to suspect Eligard(drug and device) as it could be attributed to underlying prostate cancer which is known to progress despite treatment.

Additional Information (Continuation...)

Lab Result :

Test Name	Test Date	Test Result	Normal Value
PSA	28/Mar/2025		
PSA			

Test Result (Code) / Result Unstructured Data (free text) :

Continuation Sheet for CIOMS report

1) Test Name: PSA

Result Unstructured Data (free text) : 70

Test Date: 28/Mar/2025

2) Test Name: PSA

Result Unstructured Data (free text) : 11

Test Date:

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

Product-Reaction Level

1) Drug	:	Eligard® (Leuprolide acetate)
Active Substance	:	1) Leuprolide acetate
Drug Characterization	:	Suspect
Form Strength	:	1) 45 Milligram
Form of Admin	:	1) Injection
Lot Number	:	1) 15276CUY; Unk; Unk
Daily Dose	:	(45 milligram(s), 1 in 6 Month)
Route of Admin	:	1) Subcutaneous
Indications	:	1) Prostate cancer [10060862 - Prostate cancer]
Therapy Dates	:	1) From : 24/Apr/2024 To :Continuing
Action(s) Taken With Drug	:	Dose not changed

Causality

1) Increased prostate antigen/prostate antigen laboratory test where it was increased to 70 (Prostatic specific antigen increased - 10036975, Prostatic specific antigen increased - 10036975)

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

Labeling :

1) Increased prostate antigen/prostate antigen laboratory test where it was increased to 70
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) 15276CUY; Unk; Unk
Indications	:	1) Prostate cancer [10060862 - Prostate cancer]
Action(s) Taken With Drug	:	Not applicable

Causality

1) Increased prostate antigen/prostate antigen laboratory test where it was increased to 70 (Prostatic specific antigen increased - 10036975, Prostatic specific antigen increased - 10036975)

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

Labeling :

1) Increased prostate antigen/prostate antigen laboratory test where it was increased to 70
CORE

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

Dosage Text :

Drug 1 :Eligard®

1) Expiration Date-Aug-2026; Unk; Unk

Drug 2 :Eligard® Unspecified Device

1) Expiration Date-Aug-2026; Unk; Unk

22.CONCOMITANT DRUG(S) (Continuation...)

Continuation Sheet for CIOMS report

1). Drug	:	BICALUTAMIDE
Active Substance	:	1) BICALUTAMIDE
Form Strength	:	
Indications	:	1) Product used for unknown indication [10070592 - Product used for unknown indication]