SUSPECT ADVERSE REACTION REPORT

PA-Tolmar-TLM-2025-00747

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
RQO	PANAMA	23	Jan	1942	83	Male		Feb	2025

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

1) Suspension of treatment (Therapy cessation (10065154), Therapy cessation (10065154))
(/Feb/2025 -) - Unknown
2) PSA (Prostatic Antigen) not expected (Prostatic specific antigen abnormal (10058012), Prostatic specific antigen abnormal (10058012))
(/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) (Injection)(Unknown)

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) (26/Aug/2024 -)	

III. CONCOMITANT DRUG(S) AND HISTORY

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

1)Doxazosin(DOXAZOSIN)

Cont..

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

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

Cont..

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-2025-00747
24c. DATE RECEIVED BY MANUFACTURER: 08/Apr/2025	24d. REPORT SOURCE: ☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT: 31/May/2025	25a. REPORT TYPE: ☑ 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 via the ‘ASOFARMA A TU LADO' Patient Support Program (reference number: PA-ADIUM-PA-0033-20250408) on 08-Apr-2025 from a consumer (patient's son) (non-healthcare professional) regarding an 83 year old male patient who experienced non-serious events of ‘‘suspension of treatment'' (therapy cessation) and ‘‘PSA (Prostatic Antigen) not expected'' (Prostatic specific antigen abnormal) during Eligard (Leuprolide acetate) of 45 mg for prostate cancer. The needle component of the constituent device was not identified in the report. The report was sent to Tolmar on 09-Apr-2025.

The patient's medical history reported as cardiomegaly, and current condition included prostate cancer.

Concomitant medications included doxazosin and other therapeutic product.

On 26-Aug-2024, the patient began receiving Eligard 45 mg for every 6 months subcutaneously for prostate cancer (Lot numbers and Expiration dates were not provided).

On an unknown date, patient son's reported that at the end of Feb-2025, the patient had an appointment with the specialist (physician), who discontinued the patient's Eligard treatment because, at the beginning of Mar-2025, he had his last PSA (Prostate Aging Antigen) tests, and the levels had not dropped. He did not remember what the previous result was, only that they were not what the specialist expected. He mentions that the patient does not have a next appointment with the physician.

On an unknown date in late Feb-2025 and early Mar-2025, the patient was scheduled to receive Eligard but it was not administered, and the last application was in 2024. No further details were available.

Corrective treatment was not reported.

Relevant test results included:
On an unknown date in Mar-2025: Prostatic specific antigen: abnormal (Ref range: Not provided)

Action taken with Eligard in response to the events therapy cessation and prostatic specific antigen abnormal was drug withdrawn. De-challenge and re-challenge were not applicable.

The outcome of therapy cessation was unknown.

The outcome of prostatic specific antigen abnormal was not recovered.

The reporter did not assess the seriousness of therapy cessation and prostatic specific antigen abnormal.

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

No further queries were raised.

On 19-May-2025, the follow up from Panama was received by Adium via the ‘ASOFARMA A TU LADO' Patient Support Program (reference number: PA-ADIUM-PA-0033-20250408). New information included: it was confirmed that no further information could be obtained since the patient was inactive in the CRM.

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

Prostatic specific antigen abnormal>Eligard>Listed as per CCDS>07-Nov-2024
Prostatic specific antigen abnormal>Eligard>Listed as per USPI>Feb-2025
Prostatic specific antigen abnormal>Eligard unspecified device>Listed as per USPI>Feb-2025
Prostatic specific antigen abnormal>Eligard>Listed as per Canadian monograph>02-Apr-2025

Company Remarks (Sender's Comments) :

Evaluator comment (Tolmar): This is regarding a 83 year old elderly male patient who had therapy cessation (‘‘suspension of treatment'') and prostatic specific antigen abnormal (‘‘PSA (Prostatic Antigen) not expected'') during Eligard (leuprolide acetate) 45 mg therapy for prostate cancer. Tolmar assessed the event as non-serious since they do not meet the ICH seriousness criteria and are not IME event. The reported event therapy cessation and prostatic specific antigen abnormal were assessed as not related to Eligard (drug and device) as the event occurred due to human action and underlying prostate cancer is a major contributing factor.

Continuation Sheet for CIOMS report

Additional Information (Continuation...)

Lab Result :

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

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

1) Test Name: PSA

Result Unstructured Data (free text) : PSA abnormal

Test Date: /Mar/2025

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) Unknown
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 : 26/Aug/2024 To :
Action(s) Taken With Drug : Drug withdrawn

Causality

1) Suspension of treatment (Therapy cessation - 10065154, Therapy cessation - 10065154)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

2) PSA (Prostatic Antigen) not expected (Prostatic specific antigen abnormal - 10058012, Prostatic specific antigen abnormal - 10058012)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) Suspension of treatment
CORE UnLabeled

2) PSA (Prostatic Antigen) not expected
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) Unknown
Route of Admin : 1) Subcutaneous
Indications : 1) Prostate cancer [10060862 - Prostate cancer]
Action(s) Taken With Drug : Not applicable

Causality

1) Suspension of treatment (Therapy cessation - 10065154, Therapy cessation - 10065154)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

2) PSA (Prostatic Antigen) not expected (Prostatic specific antigen abnormal - 10058012, Prostatic specific antigen abnormal - 10058012)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable

Continuation Sheet for CIOMS report

ReChallenge : Not Applicable

Labeling :

1) Suspension of treatment
CORE
2) PSA (Prostatic Antigen) not expected
CORE

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

1). Drug	:	Doxazosin
Active Substance	:	1) DOXAZOSIN
Form Strength	:	
Indications	:	1) drug use for unknown indication [10057097 - Drug use for unknown indication]

2). Drug	:	OTHER THERAPEUTIC PRODUCTS
Active Substance	:	1) OTHER THERAPEUTIC PRODUCTS
Form Strength	:	
Indications	:	1) drug use for unknown indication [10057097 - Drug use for unknown indication]

23. OTHER RELEVANT HISTORY (Continuation...)

2) BIG HEART (10007632 , Cardiomegaly)