SUSPECT ADVERSE REACTION REPORT

PA-TOLMAR, INC.-25PA057645

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	4-6 REACTION ONSET		
		Day	Month	Year	Years		Day	Month	Year
GAMK	PANAMA	24	Sep	1939	85	Male		Feb	2025

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

1) levels are below normal (Laboratory test abnormal (10023547), Laboratory test abnormal (10023547))
(/Feb/2025 -) - Not Recovered/Not Resolved/Ongoing
2) FREQUENT URINATION AT NIGHT (Nocturia (10029446), Nocturia (10029446))
(/Feb/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)(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)

Cont..

16. ROUTE(S) OF ADMINISTRATION

1) 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) (11/Sep/2024 - ongoing)	

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	PA-TOLMAR, INC.-25PA057645
24c. DATE RECEIVED BY MANUFACTURER	24d. REPORT SOURCE
20/Aug/2025	☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT	25a. REPORT TYPE
25/Aug/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 via Patient Support Program (reference number: PA-ADIUM-PA-0016-20250313) on 13-MAR-2025 from a Consumer/Other Non-Health Prof regarding an Elderly 85-years-old Male patient who experienced "frequent urination at night" (Nocturia), during Eligard (Leuprolide acetate) 45 milligram therapy for Prostate cancer. The needle component of the constituent device was not identified in the report. XTANDI (Enzalutamide) was also considered as suspect. The report was sent to Tolmar on 14-MAR-2025.

The patient's medical history and current condition included Prostate cancer.

Concomitant medications were not reported.

On 11-SEP-2024, the patient began receiving Eligard 45 milligram, q 6 month via Subcutaneous use for Prostate cancer (Lot numbers and Expiration dates were not reported).

On an unspecified date in FEB-2025, at an unknown time after the most recent dose of Eligard, the patient experienced frequent urination at night and had to get up 4 to 5 times in the middle of the night to urinate. The patient's physician was aware of the situation.

Corrective treatment was not reported.

Action taken with Eligard in response to the event was Dose Not Changed. De-challenge and re-challenge were Not applicable.

The outcome of Nocturia was Not Recovered.

The reporter did not assess the seriousness or causality of the event in relationship to Eligard and Eligard unspecified device.

On 21-Apr-2025, the follow up information was received via Adium (reference number: PA-ADIUM-PA-0016-2025031) from a consumer (consumer or non-healthcare professional) and sent to Tolmar on 22-Apr-2025. New information included: Batch lot number and expiration date of Eligard and Xatandi route of administration (oral and dosage form: capsule) was added.

On 11-SEP-2024, the patient began receiving Eligard 45 milligram, q 6 months via Subcutaneous use for Prostate cancer (Lot number: 15276CUY and Expiration date: Aug-2026).

The listedness of nocturia was retained as previously assessed.

On 20-Aug-2025, follow up information was received by Adium via Patient Support Program (reference number: (PA-ADIUM-PA-0016-20250313 (2)), from a consumer and sent to Tolmar on 21-Aug-2025. New information included: action taken for co-suspect product Xtandi was changed to drug withdrawn, new lab test was added and new event ‘levels are below normal' (Laboratory test abnormal) was added. Narrative was updated.

As reported in the follow-up, it was mentioned that on 20-Aug-2025, the physician discontinued the medication (Xtandi) because the patient's levels were below normal. The patient stated that he stopped the medication a while ago, referring to the discontinuation of treatment.

Relevant test results included:
On an unknown date, laboratory test: levels were below normal (Ref. range: Not provided).

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

The outcome of laboratory test abnormal was not recovered.

The reporter did not assess the seriousness of laboratory test abnormal.

The reporter did not provide the causality of laboratory test abnormal in relationship to Eligard and Eligard unspecified device.

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

Listedness:

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

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

Continuation Sheet for CIOMS report

Company Remarks (Sender's Comments) :

Causality was retained as previously assessed:
Nocturia: related to drug and not related to device.

Evaluators comments : As per company conventions, "frequent urination at night" (Nocturia) and "levels are below normal" (laboratory test abnormal) 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.

Additional Information (Continuation...)

Lab Result :

Test Name	Test Date	Test Result	Normal Value
LABORATORY TEST	Unknown		

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

1) Test Name: LABORATORY TEST

Result Unstructured Data (free text) : levels were below normal

Test Date: Unknown

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) 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 : 11/Sep/2024 To :Continuing
Action(s) Taken With Drug : Dose not changed

Causality

1) levels are below normal (Laboratory test abnormal - 10023547, Laboratory test abnormal - 10023547)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
2) FREQUENT URINATION AT NIGHT (Nocturia - 10029446, Nocturia - 10029446)
Causality as per reporter : Not Reported
Causality as per Mfr : Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) levels are below normal
CORE
2) FREQUENT URINATION AT NIGHT
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

Continuation Sheet for CIOMS report

1) levels are below normal (Laboratory test abnormal - 10023547, Laboratory test abnormal - 10023547)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
2) FREQUENT URINATION AT NIGHT (Nocturia - 10029446, Nocturia - 10029446)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) levels are below normal
CORE
2) FREQUENT URINATION AT NIGHT
CORE

3) Drug : Xtandi
Active Substance : 1) ENZALUTAMIDE
Drug Characterization : Suspect
Form of Admin : 1) Capsule
Lot Number : 1) Unknown
Daily Dose : (160 milligram(s), 1 in 1 Day)
Route of Admin : 1) Oral
Indications : 1) Prostate cancer [10060862 - Prostate cancer]
Therapy Dates : 1) From : 01/May/2024 To :20/Aug/2025
Therapy Duration : 1) 477 Days
Action(s) Taken With Drug : Drug withdrawn

Causality

1) levels are below normal (Laboratory test abnormal - 10023547, Laboratory test abnormal - 10023547)
Causality as per reporter : Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
2) FREQUENT URINATION AT NIGHT (Nocturia - 10029446, Nocturia - 10029446)
Causality as per reporter : Not Reported
DeChallenge : Not applicable
ReChallenge : Not Applicable

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

Dosage Text :

Drug 1 :Eligard®

1) 45 milligram, q 6 month

Drug 3 :XTANDI

1) 160 milligram daily