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
G-M	PANAMA	24	Sep	1939	85	Male		Feb	2025

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

1) FREQUENT URINATION AT NIGHT (Nocturia (10029446), Nocturia (10029446))
(/Feb/2025 -) - Not Recovered/Not Resolved/Ongoing

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..

15. DAILY DOSE(S)

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

Cont..

16. ROUTE(S) OF ADMINISTRATION

1) Subcutaneous

Cont..

17. INDICATION(S) FOR USE

1) Prostate cancer [10060862 - Prostate cancer]

Cont..

18. THERAPY DATE(S) (from/to)

1) (11/Sep/2024 - ongoing)

19. THERAPY DURATION

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

21. DID EVENT REAPPEAR AFTER REINTRODUCTION ☐ YES ☐ NO ☑ NA

(NA : Not Applicable)

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
debbie.maierhofer@tolmar.comand+1-4129158447

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

24.REPORT NULLIFIED ☐ YES ☐ NO

24b. MFR CONTROL NO.

PA-TOLMAR, INC.-25PA057645

24c. DATE RECEIVED BY MANUFACTURER

21/Apr/2025

24d. REPORT SOURCE ☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL

DATE OF THIS REPORT

02/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 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.

Company Remarks (Sender's Comments) :

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

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) 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) FREQUENT URINATION AT NIGHT
CORE Labeled

Continuation Sheet for CIOMS report

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

Causality

1) FREQUENT URINATION AT NIGHT (Nocturia - 10029446, Nocturia - 10029446)
Causality as per reporter : Not Reported

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

Dosage Text :

Drug 1 :Eligard®

1) 45 milligram, q 6 month

Drug 3 :XTANDI

1) 160 milligram daily