CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

PA-TOLMAR, INC.-24PA051020

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
T-L	PANAMA	29	May	1952	72	Male		Jul	2024

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

1) Not in good condition, because on July 3, 2024 he underwent prostate surgery (General physical health deterioration (10049438), General physical health deterioration (10049438))
(/Jul/2024 -) - Unknown
2) unable to apply his December dose due to lack of financial mean (Temporary interruption of therapy (10075804), Therapy interrupted (10066377))
(/Dec/2024 -) - Unknown

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) (14/Jun/2024 -)	

III. CONCOMITANT DRUG(S) AND HISTORY

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

1)FOSFOCIL FOSFOMYCIN SODIUM

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
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.-24PA051020
24c. DATE RECEIVED BY MANUFACTURER: 10/Jun/2025	24d. REPORT SOURCE: ☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT: 20/Jun/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 “Asofarma a tu Lado” (reference number: PA-ADIUM-PA-0040-20240712) on 12-JUL-2024 from a Consumer/Other Non-Health Prof regarding an Elderly 72 Years old Male patient who experienced the medically significant event of Not in good condition, because on July 3, 2024 he underwent prostate surgery (General physical health deterioration), 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-JUL-2024.

The patient's medical history and current conditions included Prostate cancer, Prostatic operation, Catheter placement (he was using the catheter because it had become clogged (i.e. it had become blocked), Catheter removal, Urinary tract infection.

Concomitant medications included FOSFOCIL (fosfomycin sodium), CALUTOL (Bicalutamide)

On 14-JUN-2024, the patient began receiving Eligard 45 milligram, q 6 month via Subcutaneous use for Prostate cancer (Lot details were not reported). In JUL-2024, at an unknown amount of time after the most recent dose of Eligard, the patient was not in good condition, because on 03-JUL-2024, he underwent prostate surgery (reason was unknown). Corrective treatment was not reported. By the time of the report, he was waiting for the doctor's indication as to whether to continue with Eligard, or what would be the next step to follow. Action taken with Eligard in response to the event was Unknown. De-challenge and re-challenge were Unknown. The outcome of General physical health deterioration was Unknown.

Relevant test results included:
Unknown date: Culture urine: the patient had a bacterium (Ref range: Not provided)

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

On 10-Jun-2025, follow-up information was received by Adium via Patient Support Program “Asofarma a tu Lado” (reference number: PA-ADIUM-PA-0040-20240712) from a consumer (non-healthcare professional) and sent to Tolmar on 11-Jun-2025. New information included: added a new non-serious event of "unable to apply his December dose due to lack of financial mean" (therapy interrupted).

On an unknown date in Dec-2024, the patient indicated that his last application was in Jun-2024, and he was unable to apply his December dose due to lack of financial means.

Corrective treatment was not reported.

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

The outcome of therapy interrupted was Unknown.

The reporter did not assess the seriousness of therapy interrupted.

The reporter did not provide the causality of therapy interrupted in relationship to Eligard and Eligard unspecified device.

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

Listedness

Listedness of the event general physical health deterioration is retained as per previous assessment.

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

Company Remarks (Sender's Comments) :

Evaluator comment (Tolmar): This is regarding an elderly 72-year-old male patient who experienced general physical health deterioration (Not in good condition, because on July 3, 2024 he underwent prostate surgery) during Eligard (Leuprolide acetate) 45 mg therapy for prostate cancer. Tolmar assessed the event as serious (MS) based on the reported seriousness criteria. Event is assessed as not related to Eligard (drug and device), as per case context it is likely due to prostate surgery patient underwent. Prostate cancer is a confounder.

FU-Event therapy interrupted (unable to apply his December dose due to lack of financial mean) added. Tolmar assessed the event as non-serious since it does not meet the ICH seriousness criteria and is not an IME event. The reported event therapy interrupted was assessed as not related to Eligard (drug and device) as the event occurred with the product due to human action, rather due to the drug. Causality of the event general physical health deterioration is retained as per previous assessment.

Continuation Sheet for CIOMS report

Additional Information (Continuation...)

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

1) Test Name: URINE CULTURE TEST

Result Unstructured Data (free text) : the patient had a bacterium

Test Date:

Lab Comments :

1) Test Name : URINE CULTURE TEST

Lab Comments : the patient had a bacterium

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 : 14/Jun/2024 To :Unknown
Action(s) Taken With Drug	:	Unknown

Causality

1) Not in good condition, because on July 3, 2024 he underwent prostate surgery (General physical health deterioration - 10049438, General physical health deterioration - 10049438)

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

2) unable to apply his December dose due to lack of financial mean (Temporary interruption of therapy - 10075804, Therapy interrupted - 10066377)

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

Labeling :

1) Not in good condition, because on July 3, 2024 he underwent prostate surgery
CORE UnLabeled
2) unable to apply his December dose due to lack of financial mean
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
Indications	:	1) prostate cancer [10060862 - Prostate cancer]
Action(s) Taken With Drug	:	Not applicable

Causality

1) Not in good condition, because on July 3, 2024 he underwent prostate surgery (General physical health deterioration - 10049438, General physical health deterioration - 10049438)

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

2) unable to apply his December dose due to lack of financial mean (Temporary interruption of therapy - 10075804, Therapy interrupted - 10066377)

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

Labeling :

Continuation Sheet for CIOMS report

1) Not in good condition, because on July 3, 2024 he underwent prostate surgery
CORE
2) unable to apply his December dose due to lack of financial mean
CORE

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

Dosage Text :

Drug 1 :Eligard®

1) 45 milligram, q 6 month

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

1). Drug	:	FOSFOCIL [FOSFOMYCIN SODIUM]
Active Substance	:	1) FOSFOMYCIN SODIUM
Form Strength	:	
Daily Dose	:	1) 1500 milligram(s) (500 milligram(s), 1 in 8 Hour)
Indications	:	1) urinary tract infection [10046571 - Urinary tract infection]

2). Drug	:	CALUTOL
Active Substance	:	1) BICALUTAMIDE
Form Strength	:	
Indications	:	1) Drug use for unknown indication [10057097 - Drug use for unknown indication]

23. OTHER RELEVANT HISTORY (Continuation...)

2) PROSTATE SURGERY (10073343 , Prostate surgery) (Continuing : NO)

3) REMOVED THE CATHETER (10052916 , Catheter removal) (Continuing : NO)

4) URINARY TRACT INFECTION (10046571 , Urinary tract infection)

5) USED A CATHETER (10052915 , Catheter placement)