SUSPECT ADVERSE REACTION REPORT

GT-TOLMAR, INC.-24GT055046

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
ICMS	GUATEMALA	02	Jan	1951	73	Male			

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

1) RENAL FAILURE (Renal failure (10038435), Renal failure (10038435))
Not Recovered/Not Resolved/Ongoing

2) WHITE PUS COMES OUT IN HIS URINE (Urine containing pus (10046621), Pyuria (10037686))
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)(Unknown)

Cont..

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

15. DAILY DOSE(S)

1) (22.5 milligram(s), 1 in 3 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) (27/May/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) FOLEY CATHETER (10016892, Foley catheter) (//2024 -)

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: N/A
EudraCT Number:
Protocol No.: N/A
Center No.:
Subject Id :

24.REPORT NULLIFIED	24b. MFR CONTROL NO.
☐ YES ☐ NO	GT-TOLMAR, INC.-24GT055046
24c. DATE RECEIVED BY MANUFACTURER: 20/Apr/2025	24d. REPORT SOURCE: ☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT: 03/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 GUATEMALA was received by Adium PSP - Prevenfuturo (reference number: GT-ADIUM-GT-0560-20241216) on 16-DEC-2024 from a Consumer regarding an Elderly 73 Years old Male patient who experienced serious (medically significant) event of Renal failure (Renal failure) and non-serious event of White pus comes out in his urine (Urine containing pus) during Eligard (Leuprolide acetate) 22.5 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 17-DEC-2024.

The patient's medical history and current conditions included Prostate cancer, Haemodialysis, Bladder catheterisation.

Concomitant medications were not reported.

On 27-MAY-2024, the patient began receiving Eligard 22.5 milligram, q 3 month via Subcutaneous use for Prostate cancer (Lot numbers and Expiration date were not reported).

On an unknown date, approximately 2 months ago in 2024, a Foley catheter was placed (unknown reason).

On an unknown date, at unknown amount of time after the most recent dose of Eligard, the patient experienced white pus coming out in his urine which was observed in Foley catheter.

On 27-NOV-2024, 6 months 1 day after the most recent dose of Eligard, the patient experienced renal failure. The patient started hemodialysis twice a week to treat Renal failure.

Corrective treatment for hemodialysis included hemodialysis.

Corrective treatment was not reported for Urine containing pus.

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

The outcome of Renal failure and Urine containing pus was not recovered.

The reporters did not assess the seriousness and causality of the events in relationship to Eligard and Eligard unspecified device.

On 20-Apr-2025, the follow up received which included no new information.

Note: The previous vendor had already changed the study type from spontaneous to study (No new information received).

Listedness:

Listedness of events renal failure and pyuria retained as per previous assessment.

Company Remarks (Sender's Comments) :

Evaluator Comment (Tolmar): This is regarding an elderly 73-year-old male patient who experienced renal failure (Renal failure) and pyuria (White pus comes out in his urine) during Eligard (Leuprolide acetate) 22.5 mg therapy for prostate cancer. Tolmar assessed the event renal failure as serious (MS) as it is an IME event and requiring significant medical intervention (Hemodialysis) and pyuria is a non-serious event as it did not meet ICH seriousness criteria. Both the events are considered as not related to Eligard (drug and device) as there is no reasonable evidence and they are inconsistent with the product safety profile. Etiopathogenesis of both the events do not support their causal association with Eligard. Information regarding relevant medical history, lab data and concomitants if received would help in better understanding of the causality of the events.

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	:	(22.5 milligram(s), 1 in 3 Month)
Route of Admin	:	1) Subcutaneous
Indications	:	1) Prostate cancer [10060862 - Prostate cancer]
Therapy Dates	:	1) From : 27/May/2024 To :Continuing
Action(s) Taken With Drug	:	Dose not changed

Continuation Sheet for CIOMS report

Causality

1) RENAL FAILURE (Renal failure - 10038435, Renal failure - 10038435)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
2) WHITE PUS COMES OUT IN HIS URINE (Urine containing pus - 10046621, Pyuria - 10037686)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) RENAL FAILURE
CORE UnLabeled
2) WHITE PUS COMES OUT IN HIS URINE
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) RENAL FAILURE (Renal failure - 10038435, Renal failure - 10038435)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
2) WHITE PUS COMES OUT IN HIS URINE (Urine containing pus - 10046621, Pyuria - 10037686)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) RENAL FAILURE
CORE
2) WHITE PUS COMES OUT IN HIS URINE
CORE

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

Dosage Text :

Drug 1 :Eligard®

1) 22.5 milligram, q 3 month

23. OTHER RELEVANT HISTORY (Continuation...)

2) HEMODIALYSIS (10019480 , Hemodialysis) (27/Nov/2024 -) (Continuing : YES)

3) PROSTATE CANCER (10060862 , Prostate cancer) (Continuing : YES)