SUSPECT ADVERSE REACTION REPORT

DO-Tolmar-TLM-2025-01602

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE Years	3. SEX	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year			Day	Month	Year	
ECT	DOMINICAN Cont..	05	May	1936	89	Male			2025	

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

1) Kidney stones (Kidney stones (10023437), Nephrolithiasis (10029148))
(//2025 -) - Not Recovered/Not Resolved/Ongoing
2) vesical balloon (Urinary retention (10046555), Urinary retention (10046555))
(//2025 -) - Not Recovered/Not Resolved/Ongoing
3) Inguinal hernia (Inguinal hernia (10022016), Inguinal hernia (10022016))
(//2025 -) - Not Recovered/Not Resolved/Ongoing
4) Anemia (Anemia (10002272), Anaemia (10002034))
(//2025 -) - Recovering/Resolving

Cont..

- ☐ 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) (22.5 Milligram, Injection)(15109CUY; UNK; UNK)(22.5 Milligram, Injection)(Unknown)

Cont..

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
1) (22.5 milligram(s), 1 in 3 Month)	1) Subcutaneous
2) (22.5 milligram(s), 1 in 3 Month)	2) 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) (/Feb/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
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	DO-Tolmar-TLM-2025-01602
24c. DATE RECEIVED BY MANUFACTURER	24d. REPORT SOURCE
08/May/2025	☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT	25a. REPORT TYPE
19/May/2025	☑ INITIAL ☐ FOLLOWUP

= Continuation attached sheet(s)..

Continuation Sheet for CIOMS report

1a. COUNTRY

DOMINICAN REPUBLIC

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

Event Description :

This study report from Dominican Republic was received by Adium via patient support program (Asofarma A Tu Lado) (reference number: DO-ADIUM-DO-0034-20250508) on 08-May-2025, from a consumer (non-healthcare professional) regarding an elderly-89-year-old male patient who experienced serious events of ‘kidney stones' (nephrolithiasis) (medically significant), ‘vesical balloon' (urinary retention) (medically significant) and non-serious events of ‘anemia' (anaemia) and ‘inguinal hernia' (inguinal hernia) during Eligard (leuprolide acetate) 22.5 mg therapy for prostate cancer. The needle component of the constituent device was not identified in the report. The report was sent to Tolmar on 12-May-2025.

The patient's medical history was unknown, and current condition included prostate cancer.

Concomitant medications were unknown.

On an unknown date in Feb-2024, the patient began receiving Eligard 22.5 mg every 3 months via subcutaneous route for prostate cancer (Lot numbers: 15109CUY; UNK; UNK expiration dates: May-2026).

On 07-May-2025, the patient received Eligard 22.5 mg every 3 months via subcutaneous route for prostate cancer (Lot numbers and Expiration dates were unknown).

On an unknown date and month in year 2025, the patient had anemia, hemoglobin level of 11g/dl, bladder occlusion due to which he was unable to urinate for which the indwelling urinary catheter was placed, kidney stones which were seen during abdominal ultrasound and an inguinal hernia. No further details were provided.

Corrective treatment included insertion of urinary catheter for urinary retention.

Relevant test results included:

On an unknown date: Haemoglobin: 11g/dl (Ref range: not provided).
On an unknown date: Ultrasound abdomen: kidney stones (Ref range: not provided).

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

The outcome of anaemia was resolving.

The outcome of nephrolithiasis, urinary retention and inguinal hernia was not resolved.

The reporter did not assess the seriousness of nephrolithiasis, urinary retention, anaemia and inguinal hernia.

The reporter did not provide the causality of nephrolithiasis, urinary retention, anaemia and inguinal hernia in relation to Eligard and Eligard Unspecified Device.

No further information is expected as the reporter did not consent to be contacted for follow up.

Listedness

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

Urinary retention>Eligard>Listed as per CCDS>07-Nov-2024
Urinary retention>Eligard>Listed as per USPI>Feb-2025
Urinary retention>Eligard unspecified device>Listed as per USPI>Feb-2025
Urinary retention>Eligard>Listed as per Canadian monograph>02-Apr-2025

Inguinal hernia>Eligard>Unlisted as per CCDS>07-Nov-2024
Inguinal hernia>Eligard>Unlisted as per USPI>Feb-2025
Inguinal hernia>Eligard unspecified device>Unlisted as per USPI>Feb-2025
Inguinal hernia>Eligard>Unlisted as per Canadian monograph>02-Apr-2025

Anaemia>Eligard>Listed as per CCDS>07-Nov-2024
Anaemia>Eligard>Listed as per USPI>Feb-2025

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Anaemia>Eligard unspecified device>Listed as per USPI>Feb-2025
Anaemia>Eligard>Listed as per Canadian monograph>02-Apr-2025

Company Remarks (Sender's Comments) :

Evaluator comment (Tolmar): This is regarding 89-year-old elderly male patient who had nephrolithiasis (kidney stones), urinary retention (vesical balloon), anaemia (anaemia) and ‘inguinal hernia' (inguinal hernia) during Eligard (leuprolide acetate) 22.5 mg therapy for prostate cancer. Tolmar assessed the events nephrolithiasis and urinary retention as serious (medically significant). Tolmar assessed other events as non-serious since they do not meet the ICH seriousness criteria and are not an IME event. The reported events were assessed as not related to Eligard (drug and device) considering the know safety profile of drug and nature of events. The events urinary retention and anemia are confounded by underlying prostate cancer.

Additional Information (Continuation...)

Lab Result :

Test Name	Test Date	Test Result	Normal Value
ABDOMINAL ULTRASOUND			
HAEMOGLOBIN		11 gram per decilitre	

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

1) Test Name: ABDOMINAL ULTRASOUND

Result Unstructured Data (free text) : Kidney stones
Test Date:

14.SUSPECT DRUG(S) (Continuation...)

Product-Reaction Level

1) Drug : Eligard® (Leuprolide acetate)
Active Substance : 1) Leuprolide acetate
Drug Characterization : Suspect
Form Strength : 1) 22.5 Milligram
2) 22.5 Milligram
Form of Admin : 1) Injection
2) Injection
Lot Number : 1) 15109CUY; UNK; UNK
2) Unknown
Daily Dose : (22.5 milligram(s), 1 in 3 Month)
(22.5 milligram(s), 1 in 3 Month)
Route of Admin : 1) Subcutaneous
2) Subcutaneous
Indications : 1) Prostate cancer [10060862 - Prostate cancer]
Therapy Dates : 1) From : /Feb/2024 To :Continuing
2) From : 07/May/2025 To :Continuing
Action(s) Taken With Drug : Dose not changed

Causality

1) Kidney stones (Kidney stones - 10023437, Nephrolithiasis - 10029148)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
2) vesical balloon (Urinary retention - 10046555, Urinary retention - 10046555)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
3) Inguinal hernia (Inguinal hernia - 10022016, Inguinal hernia - 10022016)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable

Continuation Sheet for CIOMS report

ReChallenge : Not Applicable

4) Anemia (Anemia - 10002272, Anaemia - 10002034)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) Kidney stones
CORE UnLabeled
2) vesical balloon
CORE Labeled
3) Inguinal hernia
CORE UnLabeled
4) Anemia
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) 15109CUY; UNK; UNK
Indications : 1) Prostate cancer [10060862 - Prostate cancer]
Action(s) Taken With Drug : Not applicable

Causality

1) Kidney stones (Kidney stones - 10023437, Nephrolithiasis - 10029148)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
2) vesical balloon (Urinary retention - 10046555, Urinary retention - 10046555)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
3) Inguinal hernia (Inguinal hernia - 10022016, Inguinal hernia - 10022016)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
4) Anemia (Anemia - 10002272, Anaemia - 10002034)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) Kidney stones
CORE
2) vesical balloon
CORE
3) Inguinal hernia
CORE
4) Anemia
CORE