SUSPECT ADVERSE REACTION REPORT

DO-Tolmar-TLM-2025-03691

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	
PRIVACY	DOMINICAN Cont..	17	Apr	1957	68	Male			2025	☐ PATIENT DIED ☐ LIFE THREATENING ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION ☐ RESULTS IN PERSISTENCE OR SIGNIFICANT DISABILITY/INCAPACITY ☐ CONGENITAL ANOMALY ☐ OTHER MEDICALLY IMPORTANT CONDITION

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

1) Weight gain (Weight gain (10047896), Weight increased (10047899)) (//2025 -) - Unknown

Cont..

II. SUSPECT DRUG(S)INFORMATION

14. SUSPECT DRUG(S)(include generic name)

1) Eligard® (Leuprolide acetate, Leuprolide acetate) (Suspect) (Injection)(14330B1; 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)

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) (/Dec/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) (//2024 -) (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	DO-Tolmar-TLM-2025-03691
24c. DATE RECEIVED BY MANUFACTURER 17/Jun/2025	24d. REPORT SOURCE ☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT 25/Jun/2025	25a. REPORT TYPE ☑ 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 'ASOFARMA A TU LADO' Patient Support Program (reference number: DO-ADIUM-DO-0055-20250617) on 17-Jun-2025 from a consumer (non-healthcare professional) regarding an elderly 68-year-old male patient who experienced a non-serious event of "Weight gain" (Weight increased) 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 18-Jun-2025.

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

Concomitant medications were unknown.

On an unknown date in Dec-2024, the patient began receiving Eligard 45 mg, every 6 months via subcutaneous use for prostate cancer (Lot numbers:14330B1; UNK; UNK and Expiration dates: Nov-2025; UNK; UNK).

On an unknown date and month in 2025, the patient experienced significant weight gain of 15 pounds since starting treatment. No further details were available.

Corrective treatment was not reported.

Relevant test results included:
On an unknown date and month in 2025: weight: weight gain of 15 pounds (Ref. range: Not provided).

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

The outcome of weight increased was unknown.

The reporter did not assess the seriousness of weight increased.

The reporter assessed the causality of weight increased in relationship to Eligard and Eligard unspecified device as not related.

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

On 20-Jun-2025, follow-up information was received from Adium via 'ASOFARMA A TU LADO' Patient Support Program (reference number: DO-ADIUM-DO-0055-20250617 (1)) from a consumer (non-healthcare professional) and sent to Tolmar on 20-Jun-2025. New information included: the PSP confirmed the initiation of treatment with Eligard from Dec-2024, and the internal program form was corrected. No further details were available.

Listedness:
Weight gain>Eligard>Unlisted as per CCDS>07-Nov-2024
Weight gain>Eligard>Unlisted as per USPI>Feb-2025
Weight gain>Eligard unspecified device>Unlisted as per USPI>Feb-2025
Weight gain>Eligard>Unlisted as per Canadian monograph>02-Apr-2025

Company Remarks (Sender's Comments) :

Evaluator comment (Tolmar): This case is regarding an elderly 68-year-old male patient who experienced weight increased (weight gain) during Eligard (Leuprolide acetate) 45 mg therapy for prostate cancer. Tolmar assessed the event as non-serious since it does not meet the ICH seriousness criteria and is not an IME event. The event weight increased was considered as related as the contributory role of suspect drug Eligard cannot be ruled out considering known pharmacological profile of the drug. Weight increased was assessed as not related to the device component of Eligard.

Additional Information (Continuation...)

Lab Result :

Test Name	Test Date	Test Result	Normal Value
WEIGHT	//2025		

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

1) Test Name: WEIGHT

Continuation Sheet for CIOMS report

Result Unstructured Data (free text) : weight gain of 15 pounds
Test Date: //2025

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) 14330B1; 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 : /Dec/2024 To :Continuing
Action(s) Taken With Drug : Dose not changed

Causality

1) Weight gain (Weight gain - 10047896, Weight increased - 10047899)
Causality as per reporter : Not Related
Causality as per Mfr : Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) Weight gain
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) 14330B1; UNK; UNK
Indications : 1) Prostate cancer [10060862 - Prostate cancer]
Action(s) Taken With Drug : Not applicable

Causality

1) Weight gain (Weight gain - 10047896, Weight increased - 10047899)
Causality as per reporter : Not Related
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) Weight gain
CORE

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

Dosage Text :
Drug 1 :Eligard®
1) 45 MG x 1 LIO x 1 JER, Expiry date: -Nov-2025; UNK; UNK

Drug 2 :Eligard® Unspecified Device
1) Expiry date: -Nov-2025; UNK; UNK