CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

HN-Tolmar-TLM-2025-01704

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
HLCC	HONDURAS	13	May	1960	64	Male			

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

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

1) Hot flashes (Hot flashes (10020407), Hot flush (10060800))
Not Recovered/Not Resolved/Ongoing
2) Weight gain (Weight gain (10047896), Weight increased (10047899))
Not Recovered/Not Resolved/Ongoing

Cont..

II. SUSPECT DRUG(S)INFORMATION

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

1) Eligard® (Leuprolide acetate, Leuprolide acetate) (Suspect) (45 Milligram, Injection)(L15276CUY; UNK; UNK)

Cont..

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

15. DAILY DOSE(S)

1) (45 milligram(s), 1 in 24 Week)

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) Prostatic cancer [10036946 - Prostatic cancer]

18. THERAPY DATE(S) (from/to)	19. THERAPY DURATION
1) (05/Jun/2023 - Ongoing)	

III. CONCOMITANT DRUG(S) AND HISTORY

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

1)TEOPRIN(BICALUTAMIDE)(50 Milligram, Tablet)

Cont..

23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

1) PROSTATIC CANCER (10036946, Prostatic 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	HN-Tolmar-TLM-2025-01704
24c. DATE RECEIVED BY MANUFACTURER: 12/May/2025	24d. REPORT SOURCE: ☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT: 21/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 Honduras was received by Adium via ‘ASOFARMA A TU LADO' Patient Support Program (reference number: HN-ADIUM-HN-0200-20250512) on 12-May-2025, from a consumer (family member) (non-healthcare professional) regarding an adult 64-year-old male patient who experienced non-serious events of ‘hot flashes' (hot flush) and ‘weight gain' (weight increased) during Eligard (leuprolide acetate) 45 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 13-May-2025.

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

Concomitant medication included Teoprin (bicalutamide).

On 05-Jun-2023, the patient began receiving Eligard 45 mg every 24 weeks via subcutaneous route for prostate cancer (Lot numbers: L15276CUY; UNK; UNK and expiration dates: Aug-2026; UNK; UNK).

On an unknown date, the patient experienced hot flashes and suffered from weight gain. No further details were provided.

Corrective treatment was not provided.

Relevant test results included:
On an unknown date: Weight: Gain (Ref. range: Not provided).

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

The outcome of hot flush and abnormal weight gain was not resolved.

The reporter did not assess the seriousness of event hot flush and abnormal weight gain.

The reporter assessed the causality of hot flush and abnormal weight gain in relation to Eligard and Eligard Unspecified Device as related.

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

Listedness:
Hot flush>Eligard>listed as per CCDS>07-Nov-2024
Hot flush>Eligard>listed as per USPI>Feb-2025
Hot flush>Eligard unspecified device>listed as per USPI>Feb-2025
Hot flush>Eligard>listed as per Canadian monograph>O2-Apr-2025

Weight increased>Eligard>listed as per CCDS>07-Nov-2024
Weight increased>Eligard>listed as per USPI>Feb-2025
Weight increased>Eligard unspecified device>listed as per USPI>Feb-2025
Weight increased>Eligard>listed as per Canadian monograph>O2-Apr-2025

Company Remarks (Sender's Comments) :

Evaluator comment (Tolmar): This is regarding an adult 64-year-old male patient who experienced non-serious events of hot flush (hot flashes) and weight increased (weight gain) during Eligard (leuprolide acetate) 45 mg therapy for prostate cancer. Tolmar assessed the events as non-serious since they do not meet the ICH seriousness criteria and are not IME events. The reported events hot flush and weight increased were considered as related to Eligard (drug) considering the known pharmacological profile of the drug and not related to device component of Eligard.

Additional Information (Continuation...)

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

1) Test Name: WEIGHT

Result Unstructured Data (free text) : Gain
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) 45 Milligram

Continuation Sheet for CIOMS report

Form of Admin	:	1) Injection
Lot Number	:	1) L15276CUY; UNK; UNK
Daily Dose	:	(45 milligram(s), 1 in 24 Week)
Route of Admin	:	1) Subcutaneous
Indications	:	1) Prostatic cancer [10036946 - Prostatic cancer]
Therapy Dates	:	1) From : 05/Jun/2023 To :Continuing
Action(s) Taken With Drug	:	Dose not changed

Causality

1) Hot flashes (Hot flashes - 10020407, Hot flush - 10060800)

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

2) Weight gain (Weight gain - 10047896, Weight increased - 10047899)

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

Labeling :

1) Hot flashes
CORE Labeled
2) 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) L15276CUY; UNK; UNK
Indications	:	1) Prostatic cancer [10036946 - Prostatic cancer]
Action(s) Taken With Drug	:	Not applicable

Causality

1) Hot flashes (Hot flashes - 10020407, Hot flush - 10060800)

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

2) Weight gain (Weight gain - 10047896, Weight increased - 10047899)

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

Labeling :

1) Hot flashes
CORE
2) Weight gain
CORE

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

Dosage Text :

Drug 1 :Eligard®

1) Expiration Date: -Aug-2026; UNK; UNK 45 Milligrams every 24 Weeks.

Drug 2 :Eligard® Unspecified Device

1) Expiration Date: -Aug-2026; UNK; UNK

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

1). Drug	:	TEOPRIN
Active Substance	:	1) BICALUTAMIDE
Form Strength	:	1) 50 Milligram

Continuation Sheet for CIOMS report

Form of Admin	:	1) Tablet
Daily Dose	:	1) (50 milligram(s), 1 in 1 Day)
Route of Admin	:	1) Oral
Indications	:	1) Prostatic cancer [10036946 - Prostatic cancer]