SUSPECT ADVERSE REACTION REPORT

DO-Tolmar-TLM-2025-04013

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	
AGE	DOMINICAN Cont..	08	Jul	1953	71	Male	15	Jan	2024	

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

1) Always feeling hot (Feeling hot (10016334), Feeling hot (10016334))
(15/Jan/2024 -) - Not Recovered/Not Resolved/Ongoing
2) Suspension of treatment (Therapy cessation (10065154), Therapy cessation (10065154))
(/Feb/2025 -) - Unknown

- ☐ 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) (15/Jan/2024 - /Feb/2025)	1) 384 Days

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) (//2023 - /Feb/2025) (Continuing: No)

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-2025-04013
24c. DATE RECEIVED BY MANUFACTURER: 23/Jun/2025	24d. REPORT SOURCE: ☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT: 26/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 "ASOFARMA A TU LADO" Patient Support Program (Reference number: DO-ADIUM-DO-0059-20250623 (0)) on 23-Jun-2025 from a consumer (non-healthcare professional) regarding an elderly 71-year-old male patient who experienced non-serious events of ‘‘suspension of treatment" (therapy cessation) and "Always feeling hot" (feeling hot), 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 24-Jun-2025.

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

Concomitant medication was unknown.

On 15-Jan-2024, the patient began receiving Eligard 45 mg every 6 months, via subcutaneous route, for prostate cancer (Lot numbers and Expiration dates were not provided) and from the same day he was always feeling hot.

On an unknown date in Feb-2025, the patient received the last dose of Eligard 45 mg every 6 months, via subcutaneous route for prostate cancer (Lot numbers and Expiration dates were not provided). No further details were provided.

Corrective treatment was unknown.

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

The outcome of therapy cessation was unknown.

The outcome of feeling hot was not recovered.

The reporter did not assess the seriousness of therapy cessation and feeling hot.

The reporter assessed the causality of therapy cessation and feeling hot in relationship to Eligard and Eligard unspecified device as related.

No further query was raised.

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

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

Company Remarks (Sender's Comments) :

Evaluator comment (Tolmar): This is regarding an elderly 71-year-old male patient who experienced therapy cessation (suspension of treatment) and feeling hot (Always feeling hot) during Eligard (leuprolide acetate) 45 mg therapy for prostate cancer. Tolmar assessed the reported events as non-serious since they did not meet the ICH seriousness criteria and are not IME events. Tolmar assessed feeling hot as related to Eligard drug based on nature of event and safety profile of drug. Feeling hot is assessed as not related to device component of Eligard. Therapy cessation is assessed as not related to Eligard (drug and device) as the event occurred with the product due to human action, rather than due to the drug.

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

Continuation Sheet for CIOMS report

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 : 15/Jan/2024 To :/Feb/2025
Therapy Duration	:	1) 384 Days
Action(s) Taken With Drug	:	Unknown

Causality

1) Always feeling hot (Feeling hot - 10016334, Feeling hot - 10016334)

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

2) Suspension of treatment (Therapy cessation - 10065154, Therapy cessation - 10065154)

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

Labeling :

1) Always feeling hot
CORE UnLabeled
2) Suspension of treatment
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) Always feeling hot (Feeling hot - 10016334, Feeling hot - 10016334)

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

2) Suspension of treatment (Therapy cessation - 10065154, Therapy cessation - 10065154)

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

Labeling :

1) Always feeling hot
CORE
2) Suspension of treatment
CORE