

SUSPECT ADVERSE REACTION REPORT	
DO-Tolmar-TLM-2025-04013	

## I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY DOMINICAN	2. DATE OF BIRTH			2a. AGE Years 71	3. SEX Male	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
AGE	Cont..	Day 08	Month Jul	Year 1953			Day 15	Month Jan	Year 2024	
7+13 DESCRIBE REACTION(S) (including relevant tests/lab data)										
1) death (Death (10011906), Death (10011906)) (- 26/May/2025) - Fatal 2) Always feeling hot (Feeling hot (10016334), Feeling hot (10016334)) (15/Jan/2024 - ) - Not Recovered/Not Resolved/Ongoing 3) Suspension of treatment (Therapy cessation (10065154), Therapy cessation (10065154)) (/Feb/2025 - ) - Unknown										
										<input checked="" type="checkbox"/> PATIENT DIED <input type="checkbox"/> LIFE THREATENING <input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION <input type="checkbox"/> RESULTS IN PERSISTENCE OR SIGNIFICANT DISABILITY/INCAPACITY <input type="checkbox"/> CONGENITAL ANOMALY <input type="checkbox"/> OTHER MEDICALLY IMPORTANT CONDITION

## II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)		20. DID EVENT ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA  21. DID EVENT REAPPEAR AFTER REINTRODUCTION <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA (NA : Not Applicable)
1) Eligard® (Leuprolide acetate, Leuprolide acetate) (Suspect) (Injection) (Unknown)		
15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION	
1) (45 milligram(s), 1 in 6 Month)	1) Subcutaneous	
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)		

## 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		Study Information Study Name: NA EudraCT Number: Protocol No.: NA Center No.: Subject Id :
Name : Tolmar, Inc 701 Centre Avenue Fort Collins, CO, 80526, UNITED STATES OF AMERICA Anjan.Chatterjee@tolmar.comand+1--9702124900		
24. REPORT NULLIFIED	24b. MFR CONTROL NO.	
<input type="checkbox"/> YES <input type="checkbox"/> NO	DO-Tolmar-TLM-2025-04013	
24c. DATE RECEIVED BY MANUFACTURER	24d. REPORT SOURCE	
02/Jul/2025	<input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL	
DATE OF THIS REPORT	25a. REPORT TYPE	
05/Jul/2025	<input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> 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>Listed as per CCDS>07-Nov-2024

feeling hot>Eligard>Listed as per USPI>Feb-2025

feeling hot>Eligard unspecified device>Listed as per USPI>Feb-2025

feeling hot>Eligard>Listed 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

On 02-Jul-2025, the follow up information was received by Adium via 'ASOFARMA A TU LADO' Patient Support Program (Reference number: O-ADIUM-DO-0059-20250623 (1)) from a consumer (non-healthcare professional) and sent to Tolmar on 03-Jul-2025. New information included: a new serious (death) event of 'death' (death) was added.

On 26-May-2025, the patient died due to unknown cause of death. The patient was 71 years old at the time of his death. It was unknown if an autopsy was performed. No further information was available.

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

The outcome of death was fatal.

The reporter assesses the seriousness of death as serious (death).

The reporter assessed the causality of death in relationship to Eligard and Eligard Unspecified Device as not related.

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

Death>Eligard>Unlisted as per CCDS>07-Nov-2024

## Continuation Sheet for CIOMS report

Death>Eligard>Unlisted as per USPI>Feb-2025  
 Death>Eligard unspecified device>Unlisted as per USPI>Feb-2025  
 Death>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.

Evaluator comment (Tolmar): The case is regarding an elderly 71-year-old male patient who died (death) due to unknown cause. Tolmar assessed the reported event as serious since the outcome being fatal. The causality for the reported event death is not assessable due to limited information on cause of death, events or circumstances preceding patient's death, autopsy report, relevant medical history, supportive investigations that could indicate cause of death, concomitant medications received by the patient which precludes meaningful medical assessment of the report. However, advanced age of the patient and underlying prostate cancer are pre-existing risk factors for patient's death. Death is assessed as not related Eligard device.

## 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 : (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  
 Action(s) Taken With Drug : Not applicable

## Causality

1) death (Death - 10011906, Death - 10011906 )  
 Causality as per reporter : Not Related  
 Causality as per Mfr : Not assessable  
 DeChallenge : Not applicable  
 ReChallenge : Not Applicable  
 2) 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  
 3) 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) death  
 CORE UnLabeled  
 2) Always feeling hot  
 CORE Labeled  
 3) 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

## Continuation Sheet for CIOMS report

## Causality

## 1) death (Death - 10011906, Death - 10011906 )

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

## 2) 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

## 3) 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) death

CORE

## 2) Always feeling hot

CORE

## 3) Suspension of treatment

CORE