SUSPECT ADVERSE REACTION REPORT

DO-Tolmar-TLM-2025-04795

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	4-6 REACTION ONSET		
		Day	Month	Year	Years		Day	Month	Year
DMS	DOMINICAN Cont..	03	Jan	1943	82	Male			

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

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

1) Death (Death (10011906), Death (10011906))
(- 02/Jul/2025) - Fatal

- [x] 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) (45 Milligram, Injection)(Unknown) Cont..

20. DID EVENT ABATE AFTER STOPPING DRUG? [ ] YES [ ] NO [x] 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 [x] 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) (26/Sep/2023 -)	

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) (/Nov/2022 -) (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-2025-04795
24c. DATE RECEIVED BY MANUFACTURER: 18/Jul/2025	24d. REPORT SOURCE: [x] STUDY [ ] LITERATURE [ ] HEALTH PROFESSIONAL
DATE OF THIS REPORT: 22/Jul/2025	25a. REPORT TYPE: [x] 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-0080-20250718) on 18-Jul-2025 from a consumer (non-healthcare professional) regarding an 82-year-old elderly male patient for which it was reported a serious event of "death" (Death) 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 18-Jul-2025.

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

Concomitant medications were unknown.

On an unknown date in 26-Sep-2023, the patient began receiving Eligard 45 mg, every 6 months via subcutaneous route for prostate cancer (lot numbers and expiration dates were not provided).

On 02-Jul-2025, the patient died due to unknown cause of death. The patient was 82 years old at the time of his death. It was unknown if an autopsy was performed. No further details were available.

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

The outcome of death was fatal.

The reporter assessed 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 the reporter does not consent to be contacted for follow up.

Listedness:

Death>Eligard>Unlisted as per CCDS>07-Nov-2024
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 82-year-old elderly male patient who died (Death) during Eligard (Leuprolide acetate) 45 mg therapy for prostate cancer. Tolmar assessed the event as serious (Fatal). The reported fatal event death was considered as not assessable to Eligard (drug) and not related to device considering limited information with regards to events leading to death, autopsy details, etc. Patient's elderly age and underlying prostate cancer are confounders for causality assessment.

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
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 : 26/Sep/2023 To :Not applicable
Action(s) Taken With Drug	: Not applicable

Causality

1) Death (Death - 10011906, Death - 10011906)
Causality as per reporter : Not Related

Continuation Sheet for CIOMS report

Causality as per Mfr : Not assessable
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) Death
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) Death (Death - 10011906, Death - 10011906)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) Death
CORE