SUSPECT ADVERSE REACTION REPORT

CR-Tolmar-TLM-2025-01989

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
BRA	COSTA RICA	17	Dec	1935		Male			

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

1) Passed away (Death (10011906), Death (10011906))
(- 15/May/2025) - Fatal

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- [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) (Injection)(Unknown)

Cont..

20. DID EVENT ABATE AFTER STOPPING DRUG? [ ] YES [ ] NO [x] NA

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
1) (22.5 milligram(s), 1 in 3 Month)	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

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) (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	CR-Tolmar-TLM-2025-01989
24c. DATE RECEIVED BY MANUFACTURER: 16/May/2025	24d. REPORT SOURCE: [x] STUDY [ ] LITERATURE [ ] HEALTH PROFESSIONAL
DATE OF THIS REPORT: 26/May/2025	25a. REPORT TYPE: [x] 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 Costa Rica was received by Adium via PSP SOLUTIONS (Patient Support Program) (Reference number CR-ADIUM-CR-0173-20250516) on 16-May-2025 from a patient's family member (non-healthcare professional) regarding an elderly male patient who 'Passed away' (death) during Eligard (leuprolide acetate) 22.5 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 17-May-2025.

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

Concomitant medication was unknown.

On an unknown date, the patient began receiving Eligard 22.5 mg, every 3 months, via subcutaneous route, for prostate cancer (Lot numbers and Expiration dates were not provided).

On 15-May-2025, the patient passed away and the cause of death remained unknown. The patient was 89-year-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 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 did not consent to be contacted for follow-up.

Listedness:
Death>Eligard® >unlisted as per CCDS Eligard®> 7-Nov-2024
Death>Eligard® >unlisted as per Canadian Monograph Eligard®> 2-Apr-2025
Death>Eligard®>unlisted as per USPI Eligard®>Feb-2025
Death>Eligard® Unspecified Device>unlisted as per USPI Eligard®>Feb-2025

Company Remarks (Sender's Comments) :

Evaluator comment (Tolmar): This 89-years-old male patient had experienced fatal event of death (passed away) while on 22.5 mg Eligard therapy for prostate cancer. Tolmar assessed death as serious due to fatal outcome. Causal role of Eligard (drug component) in the patient's death was not assessable as lack of information regarding 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 precludes meaningful medical assessment of the report. However, advanced age of the patient and underlying prostate cancer were pre-existing risk factors for the patient's death. Death was assessed as not related to the device component of Eligard.

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	:	(22.5 milligram(s), 1 in 3 Month)
Route of Admin	:	1) Subcutaneous
Indications	:	1) Prostate cancer [10060862 - Prostate cancer]
Action(s) Taken With Drug	:	Not applicable

Causality

1) Passed away (Death - 10011906, Death - 10011906)

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

Labeling :

Continuation Sheet for CIOMS report

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

Labeling :

1) Passed away
CORE