

SUSPECT ADVERSE REACTION REPORT	
PA-Tolmar-TLM-2025-04457	

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) F-W	1a. COUNTRY PANAMA	2. DATE OF BIRTH Day: 23, Month: Jun, Year: 1946	2a. AGE Years	3. SEX Male	4-6 REACTION ONSET Day: , Month: , Year:	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) DEATH (Death (10011906), Death (10011906)) (- //2025) - Fatal						

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) 1) Eligard® (Leuprolide acetate, Leuprolide acetate) (Suspect) (45 Milligram, Injection) (Unknown)	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
17. INDICATION(S) FOR USE 1) Prostate cancer [10060862 - Prostate cancer]	
18. THERAPY DATE(S) (from/to) 1) (01/Jul/2021 -)	19. THERAPY DURATION 1) (01/Jul/2021 -)
21. DID EVENT REAPPEAR AFTER REINTRODUCTION ☐ YES ☐ NO ☒ NA (NA : Not Applicable)	

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 Anjan.Chatterjee@tolmar.com and +1--9702124900	Study Information Study Name: NA EudraCT Number: Protocol No.: NA Center No.: Subject Id :
24. REPORT NULLIFIED ☐ YES ☐ NO	24b. MFR CONTROL NO. PA-Tolmar-TLM-2025-04457
24c. DATE RECEIVED BY MANUFACTURER 07/Jul/2025	24d. REPORT SOURCE ☒ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT 10/Jul/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 Panama was received by Adium via Patient Support Program "Asofarma a tu Lado" (reference number: PA-ADIUM-PA-0070-20250707) on 07-Jul-2025 from a consumer (non-healthcare professional) regarding an 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 08-Jul-2025.

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

Concomitant medications were unknown.

On 01-Jul-2021, 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 an unknown date in 2025, the patient died due to unknown cause of death. The patient was 79-year-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 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 79-year-old male patient who experienced fatal event of death (Death) while on Eligard(Leuprolide acetate) 45mg 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 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 : 01/Jul/2021 To :Not applicable
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

Continuation Sheet for CIOMS report

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

Labeling :

1) DEATH
CORE