CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

SV-Tolmar-TLM-2025-03521

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year	Years		Day	Month	Year	
REM	EL Cont..	27	Nov	1941		Male				

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

1) Death (Death (10011906), Death (10011906))
(- 21/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) (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) (09/Feb/2024 -)	

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

1)Aspirin(ACETYLSALICYLIC ACID)

Cont..

23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

1) STROKE (10042244, Stroke) (//2019 -)

Cont..

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	SV-Tolmar-TLM-2025-03521
24c. DATE RECEIVED BY MANUFACTURER: 09/Jul/2025	24d. REPORT SOURCE: [x] STUDY [ ] LITERATURE [ ] HEALTH PROFESSIONAL
DATE OF THIS REPORT: 12/Jul/2025	25a. REPORT TYPE: [ ] INITIAL [x] FOLLOWUP

= Continuation attached sheet(s)..

Continuation Sheet for CIOMS report

1a. COUNTRY

EL SALVADOR

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

Event Description :

This study report from El salvador was received by Adium via Patient Support Program “Asofarma a tu Lado” (reference number: SV-ADIUM-SV-0008-20250616) on 16-Jun-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 16-Jun-2025.

The patient's medical history included cerebrovascular accident and current condition included prostate cancer.

Concomitant medications were unknown.

On 09-Feb-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).

On 21-May-2025, the patient died of an unknown cause. The patient was 83-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 queries were raised.

On 09-Jul-2025, follow up information was received from El salvador was received by Adium via Patient Support Program “Asofarma a tu Lado” (reference number: SV-ADIUM-SV-0008-20250616) from a consumer (non-healthcare professional). The report was sent to Tolmar on 10-Jul-2025. New information included: Added concomitant medications and start date for prostate cancer was added. Narrative updated.

Concomitant medication included Aspirin, Inderal and Anticoagulants.

On an unknown date, the patient had no knowledge regarding the cause of death as he arrived at the hospital without signs and he suspected that it could have been due to stroke. No further details were provided.

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 83-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.

FU-Causality of the event death is retained as per previous assessment.

14.SUSPECT DRUG(S) (Continuation...)

Product-Reaction Level

1) Drug	:	Eligard® (Leuprolide acetate)
Active Substance	:	1) Leuprolide acetate

Continuation Sheet for CIOMS report

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 : 09/Feb/2024 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

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

22.CONCOMITANT DRUG(S) (Continuation...)

1). Drug : Aspirin
Active Substance : 1) ACETYLSALICYLIC ACID
Form Strength :
Indications : 1) Product used for unknown indication [10070592 - Product used for unknown indication]

2). Drug : enderal
Active Substance : 1) PROPRANOLOL HYDROCHLORIDE
Form Strength :
Indications : 1) Product used for unknown indication [10070592 - Product used for unknown indication]

3). Drug : Anticoagulants
Active Substance : 1) OTHER THERAPEUTIC PRODUCTS
Form Strength :
Indications : 1) Product used for unknown indication [10070592 - Product used for unknown indication]

23. OTHER RELEVANT HISTORY (Continuation...)

2) PROSTATE CANCER (10060862 , Prostate cancer) (/Jan/2024 -) (Continuing : YES)