SUSPECT ADVERSE REACTION REPORT

PA-Tolmar-TLM-2025-04886

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE Years	3. SEX	4-6 REACTION ONSET		
		Day	Month	Year			Day	Month	Year
EGAD	PANAMA	11	Nov	1941	83	Male		Jul	2025

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

1) Stroke (Stroke (10042244), Cerebrovascular accident (10008190))
(/Jul/2025 -) - Recovering/Resolving
2) Pneumonia (Pneumonia (10035664), Pneumonia (10035664))
(/Jul/2025 -) - Not Recovered/Not Resolved/Ongoing

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

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 ☑ 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 ☑ 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) (17/Jan/2024 -)	

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.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	PA-Tolmar-TLM-2025-04886
24c. DATE RECEIVED BY MANUFACTURER: 21/Jul/2025	24d. REPORT SOURCE: ☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT: 24/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 'ASOFARMA A TU LADO' Patient Support Program (Reference number: PA-ADIUM-PA-0078-20250721 (0)) on 21-Jul-2025 from a consumer(non-healthcare professional) regarding an elderly, 83-year-old male patient who experienced serious events of ''Stroke" (Cerebrovascular accident) (Life Threatening, hospitalization) and "Pneumonia" (Pneumonia) (Hospitalization)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 22-Jul-2025.

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

Concomitant medication was unknown.

On 17-Jan-2025, 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 Jul-2025, the patient experienced a stroke and was hospitalized, then discharged after recovery. In mid-July, he was hospitalized again for pneumonia and remained hospitalized in recovery. No further details were provided.

No further corrective treatment was reported.

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

The outcome of cerebrovascular accident was recovering and of pneumonia was not recovered.

The reporter assessed the seriousness of the cerebrovascular accident as serious (life-threatening, hospitalization) and the seriousness of pneumonia also as serious (hospitalization).

The reporter assessed the causality of cerebrovascular accident and pneumonia in relationship to Eligard and Eligard unspecified device as not related.

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

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

Stroke>Eligard® >listed as per CCDS Eligard®> 7-Nov-2024
Stroke> Eligard® >listed as per Canadian Monograph Eligard®> 2-Apr-2025
Stroke> Eligard®>listed as per USPI Eligard®>Feb-2025
Stroke> Eligard® Unspecified Device> listed as per USPI Eligard®>Feb-2025

Company Remarks (Sender's Comments) :

Evaluator comment (Tolmar): This is regarding elderly, 83-year-old male patient who experienced serious events of ''Stroke" (Cerebrovascular accident) (Life Threatening, hospitalization) and "Pneumonia" (Pneumonia) (Hospitalization) during Eligard (leuprolide acetate) 45 mg therapy for prostate cancer. Tolmar assessed the reported events as serious as it resulted in hospitalisation and medically significant nature of event, and additionally stroke was assessed as life threatening as it required immediate medical attention if not treated results in serious complication. The causality of event pneumonia was assessed as not related to Eligard (Drug and device) considering the nature of event, infectious origin and Eligard is not known to cause infections. The causality of event stroke was assessed as not related to Eligard (Drug and device) as it can be explained by hypercoagulable state due to prostate cancer and elderly age are the potential risk factors.

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]

Continuation Sheet for CIOMS report

Therapy Dates : 1) From : 17/Jan/2024 To :Unknown
Action(s) Taken With Drug : Unknown

Causality

1) Stroke (Stroke - 10042244, Cerebrovascular accident - 10008190)
Causality as per reporter : Not Related
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
2) Pneumonia (Pneumonia - 10035664, Pneumonia - 10035664)
Causality as per reporter : Not Related
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) Stroke
CORE Labeled
2) Pneumonia
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) Stroke (Stroke - 10042244, Cerebrovascular accident - 10008190)
Causality as per reporter : Not Related
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
2) Pneumonia (Pneumonia - 10035664, Pneumonia - 10035664)
Causality as per reporter : Not Related
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) Stroke
CORE
2) Pneumonia
CORE