SUSPECT ADVERSE REACTION REPORT

PA-Tolmar-TLM-2025-00938

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
V-A	PANAMA	25	Feb	1944	81	Male			

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

1) Hospitalization (No adverse event (10067482), No adverse event (10067482))
Unknown

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) (45 Milligram, Injection)(Unknown)

Cont..

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)

19. THERAPY DURATION

20. DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☑ NA

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
debbie.maierhofer@tolmar.comand+1-4129158447

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-2025-00938

24c. DATE RECEIVED BY MANUFACTURER

21/Apr/2025

24d. REPORT SOURCE ☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL

DATE OF THIS REPORT

03/May/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 Invalid case report from Panama was received by Adium (reference number: PA-ADIUM-PA-0041-20250421) via Patient Support Program on 21-Apr-2025 from a consumer (non-healthcare professional) regarding an elderly 81-year-old male patient. This report was assessed as invalid as no adverse event was reported. The reported term 'hospitalization' was not considered as an adverse event because the reason for hospitalization was not reported.

Company Remarks (Sender's Comments) :

Evaluator comment (Tolmar): This is regarding an elderly 81-year-old male patient who reported that he was hospitalised during Eligard(leuprolide acetate) 45mg therapy for prostate cancer. This report was assessed as invalid as no adverse event was reported. The reported term 'hospitalization' was not considered as an adverse event because the reason for hospitalization was not reported.

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]
Action(s) Taken With Drug	:	Not applicable

Causality

1) Hospitalization (No adverse event - 10067482, No adverse event - 10067482)

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

Labeling :

1) Hospitalization
CORE Labeled

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) Hospitalization (No adverse event - 10067482, No adverse event - 10067482)

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

Labeling :

1) Hospitalization
CORE