SUSPECT ADVERSE REACTION REPORT

SV-Tolmar-TLM-2025-01615

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	
MRHG	EL Cont..	01	May	1947	78	Male				☐ 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) Patient is hospitalized with pneumonia (Pneumonia (10035664), Pneumonia (10035664))
Unknown

II. SUSPECT DRUG(S)INFORMATION

14. SUSPECT DRUG(S)(include generic name)

1) Eligard® (Leuprolide acetate, Leuprolide acetate) (Suspect) (22.5 Milligram, Injection)(Unknown) Cont..

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

15. DAILY DOSE(S)

1) (22.5 milligram(s), 1 in 3 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) (19/Feb/2025 -)	

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	SV-Tolmar-TLM-2025-01615
24c. DATE RECEIVED BY MANUFACTURER 09/May/2025	24d. REPORT SOURCE ☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT 20/May/2025	25a. REPORT TYPE ☑ INITIAL ☐ 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-0006-20250509) on 09-May-2025, from a consumer (patient's family member) (non-healthcare professional) regarding an elderly 78 year old male patient who experienced a serious event of ''patient is hospitalized with pneumonia'' (pneumonia) (hospitalization) during Eligard 22.5mg therapy for prostate cancer. The needle component of the constituent device was not identified in the report. The report was sent to Tolmar on 12-May-2025.

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

Concomitant medications were unknown.

On 19-Feb-2025, the patient began receiving Eligard 22.5 mg every 3 months via subcutaneous route for prostate cancer (Lot numbers and Expiration dates were unknown).

On an unknown date, the patient was hospitalized with pneumonia and that in relation to next application of patient who will consult the doctor but didn't provide more details, due to short call. No further details were provided.

Further corrective treatment was unknown.

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

The outcome of pneumonia was unknown.

The reporter assesses the seriousness of pneumonia as serious (hospitalization).

The reporter provided the causality of pneumonia in relation 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.

Note: Nowhere it is mentioned in source document that patient had bacterial pneumonia except in PT hence based on medical judgement the event was coded as per reported verbatim.

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

Company Remarks (Sender's Comments) :

Evaluator comment (Tolmar): This is regarding an elderly 78-year-old male patient who reported pneumonia (patient is hospitalized with pneumonia) during Eligard 22.5mg therapy for prostate cancer. Tolmar assessed the reported event pneumonia as serious as it resulted in hospitalization. The causality of the event pneumonia was assessed as not related to suspect Eligard(drug and device) as pneumonia is of infectious origin and Eligard is not known to predispose to infections. Immunosuppression secondary to elderly age and underlying prostate cancer is a strong risk factor for pneumonia as it increased the susceptibility of patients to infections

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

Product-Reaction Level

1) Drug	: Eligard® (Leuprolide acetate)
Active Substance	: 1) Leuprolide acetate
Drug Characterization	: Suspect
Form Strength	: 1) 22.5 Milligram
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]

Continuation Sheet for CIOMS report

Therapy Dates	:	1) From : 19/Feb/2025 To :Unknown
Action(s) Taken With Drug	:	Unknown

Causality

1) Patient is hospitalized with 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) Patient is hospitalized with pneumonia
CORE

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) Patient is hospitalized with pneumonia (Pneumonia - 10035664, Pneumonia - 10035664)

Causality as per reporter	: Not Related
Causality as per Mfr	: Not Related
DeChallenge	: Not applicable
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Labeling :

1) Patient is hospitalized with pneumonia
CORE