SUSPECT ADVERSE REACTION REPORT

SI-Tolmar-TLM-2025-01726

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	
CAMN	EL Cont..	20	Nov	1945	79	Male				

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

1) Pain in the area of application (Application site pain (10003051), Application site pain (10003051))
Recovered/Resolved

- ☐ 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)(Unknown)
Cont..

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
1) (45 milligram(s), 1 in 6 Month)	1) Subcutaneous
2) (45 milligram(s), 1 in 6 Month)	2) 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
(- Ongoing)	

III. CONCOMITANT DRUG(S) AND HISTORY

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

1)BENICAR(OLMESARTAN MEDOXOMIL)
Cont..

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

1) PROSTATE CANCER (10060862, Prostate cancer) (Continuing: Yes)
Cont..

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER

Name : Tolmar, Inc
701 Centre Avenue
Fort Collins, CO, 80526, UNITED STATES OF AMERICA

Study Information
Study Name: NA
EudraCT Number:
Protocol No.: NA
Center No.:
Subject Id :

24.REPORT NULLIFIED	24b. MFR CONTROL NO.
☐ YES ☐ NO	SI-Tolmar-TLM-2025-01726
24c. DATE RECEIVED BY MANUFACTURER	24d. REPORT SOURCE
08/May/2025	☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT	25a. REPORT TYPE
19/May/2025	☑ 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 'ASOFARMA A TU LADO' Patient Support Program (reference number: SV-ADIUM-SV-0005-20250508) on 08-May-2025 from a consumer (patient's wife) (non-healthcare professional) regarding an elderly 79-year-old male patient who experienced a non-serious event of 'pain in the area of application' (Application site pain) 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 13-May-2025.

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

Concomitant medication included Benicar (olmesartan medoxomil).

On an unknown date in 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, about 2 to 3 months ago the patient received Eligard 45 mg, every 6 months via subcutaneous route for prostate cancer and experienced a lot of pain around the stomach where the Eligard was applied. The patient presented pain only with one dose, while previous doses did not cause pain, and had probably received 8 doses of Eligard.

It was reported that the patient suffered from high blood pressure long before Eligard. According to CRM data, he started Eligard on 02-Apr-2024, but his wife mentioned the treatment began in 2021.

On an unknown date in Jun-2025 (proposed commencement date), patient next application was scheduled.

Corrective treatment was not reported.

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

On an unknown date, the outcome of application site pain was resolved.

The reporter did not assess the seriousness of application site pain.

The reporter assessed the causality of application site pain in relationship to Eligard and Eligard unspecified device as related.

No further queries were raised.

Note: Since the primary reporter is patient wife and the start date of Eligard was captured as reported by her (Which will match with patient being taken 8 doses of Eligard).

Listedness:
Application site pain>Eligard>listed as per CCDS>07-Nov-2024
Application site pain>Eligard>listed as per USPI>Feb-2025
Application site pain>Eligard unspecified device>listed as per USPI>Feb-2025
Application site pain>Eligard>listed as per Canadian monograph>02-Apr-2025

Company Remarks (Sender's Comments) :

Evaluator comment (Tolmar): This is regarding an elderly 79-year-old male patient who experienced application site pain (Pain in the area of application), during Eligard (leuprolide acetate) 45 mg therapy for prostate cancer. Tolmar assessed the event as non-serious since it does not meet the ICH seriousness criteria and is not an IME event. The reported event application site pain was considered as related to Eligard (drug and device) considering the known pharmacological profile of the drug.

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
		2) Injection

Continuation Sheet for CIOMS report

Lot Number	:	1) Unknown 2) Unknown
Daily Dose	:	(45 milligram(s), 1 in 6 Month) (45 milligram(s), 1 in 6 Month)
Route of Admin	:	1) Subcutaneous 2) Subcutaneous
Indications	:	1) Prostate cancer [10060862 - Prostate cancer]
Therapy Dates	:	2) From : //2021 To :Continuing
Action(s) Taken With Drug	:	Dose not changed

Causality

1) Pain in the area of application (Application site pain - 10003051, Application site pain - 10003051)

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

Labeling :

1) Pain in the area of application
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) Pain in the area of application (Application site pain - 10003051, Application site pain - 10003051)

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

Labeling :

1) Pain in the area of application
CORE

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

1). Drug	:	BENICAR
Active Substance	:	1) OLMESARTAN MEDOXOMIL
Form Strength	:	
Daily Dose	:	1) (1 in 1 Day)
Indications	:	1) High blood pressure [10005747 - Blood pressure high]

23. OTHER RELEVANT HISTORY (Continuation...)

2) HIGH BLOOD PRESSURE (10005747 , Blood pressure high) (Continuing : YES)