SUSPECT ADVERSE REACTION REPORT

DO-Tolmar-TLM-2025-04202

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	
M-M	DOMINICAN Cont..	19	Feb	1956	69	Male		Feb	2025	

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

1) Knee pain (Knee pain (10023477), Arthralgia (10003239))
(/Feb/2025 -) - Not Recovered/Not Resolved/Ongoing
2) Glute pain (Pain (10033371), Pain (10033371))
(/Feb/2025 -) - Not Recovered/Not Resolved/Ongoing

- ☐ 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
1) (/Feb/2025 - /Feb/2025)	1) 1 Days

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	DO-Tolmar-TLM-2025-04202
24c. DATE RECEIVED BY MANUFACTURER: 24/Jun/2025	24d. REPORT SOURCE: ☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT: 03/Jul/2025	25a. REPORT TYPE: ☑ INITIAL ☐ FOLLOWUP

= Continuation attached sheet(s)..

Continuation Sheet for CIOMS report

1a. COUNTRY

DOMINICAN REPUBLIC

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

Event Description :

This study report from Dominican Republic was received by Adium via Patient Support Programme (Reference number: DO-ADIUM-DO-0061-20250624) on 24-Jun-2025 from a consumer (non-healthcare professional) regarding an elderly 69-year-old male patient who experienced non-serious events of ''knee pain'' (arthralgia), "glute pain" (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 26-Jun-2025.

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

Concomitant medication was unknown.

On 01-Jun-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 an unknown date in Feb-2025, the patient started experiencing severe glute and knee pain. His medication was suspended. No further information reported.

Corrective treatment was unknown.

Action taken with Eligard in response to events was drug withdrawn. De-challenge and re-challenge were not applicable.

The outcomes of arthralgia and pain were not resolved.

The reporter did not assess the seriousness of arthralgia and pain.

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

No further query was raised.

Note: Since stop date of treatment was given as Feb-2025, also it is captured as event onset date and action taken was reported as Drug withdrawn. Hence, as per medical judgement "suspension of medication" (therapy cessation) was not captured as an event in the case.

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

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

Company Remarks (Sender's Comments) :

Evaluator comment (Tolmar): This is regarding an elderly 69-year-old male patient who experienced non-serious events of ''knee pain'' (arthralgia), "glute pain" (pain) during Eligard (leuprolide acetate) 45 mg therapy for prostate cancer. Tolmar assessed the reported events as non-serious since they did not meet the ICH seriousness criteria. The causality of event arthralgia and pain was assessed as related to suspect drug component of Eligard(not related to device) considering the known safety profile of the drug. However, elderly age and underlying prostate cancer could be confounding factors for the events.

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	:	1) From : /Feb/2025 To :/Feb/2025
		2) From : 01/Jun/2024 To :
Therapy Duration	:	1) 1 Days
Action(s) Taken With Drug	:	Drug withdrawn

Causality

1) Knee pain (Knee pain - 10023477, Arthralgia - 10003239)

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

2) Glute pain (Pain - 10033371, Pain - 10033371)

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

Labeling :

1) Knee pain
CORE Labeled
2) Glute pain
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) Knee pain (Knee pain - 10023477, Arthralgia - 10003239)

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

2) Glute pain (Pain - 10033371, Pain - 10033371)

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

Labeling :

1) Knee pain
CORE
2) Glute pain
CORE

15. DAILY DOSE(S) (Continuation...)

Dosage Text :

Drug 1 :Eligard®

1) ELIGARD 45 MG x 1 LIO x 1 JER

2) ELIGARD 45 MG x 1 LIO x 1 JER