SUSPECT ADVERSE REACTION REPORT

GT-Tolmar-TLM-2025-05573

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE Years	3. SEX	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year			Day	Month	Year	
CVV	GUATEMALA	21	Jun	1935	90	Male		Aug	2024	

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

1) Lower back pain/ waist pain (Low back pain (10024891), Back pain (10003988)) (/Aug/2024 -) - 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)(14176A;UNK;UNK)

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) (12/Jun/2021 - Ongoing)	

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	GT-Tolmar-TLM-2025-05573
24c. DATE RECEIVED BY MANUFACTURER: 06/Aug/2025	24d. REPORT SOURCE: ☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT: 13/Aug/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 GUATEMALA was received by Adium via Patient Support Programme (Reference number: GT-ADIUM-GT-0255-20250806 (0)) on 06-Aug-2025 from a consumer (non-healthcare professional) regarding a elderly, 90-year-old male patient who experienced a non-serious event of ‘Lower back pain/ waist pain' (Back pain) during Eligard (leuprolide acetate) 45 mg therapy for prostate cancer. The needle component of the constituent device was not identidied in the report. The report was sent to Tolmar on 07-Aug-2025.

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

Concomitant medication was unknown.

On 12-Jun-2021, the patient began receiving Eligard 45 mg every 6 months via subcutaneous route for an unknown indication (Lot numbers 14176A; UNK;UNK and Expiration date -Aug-2025; UNK;UNK).

On an unknown date in Aug-2024, the patient experienced lower back pain. No further detailed were available.

Corrective treatment was not reported.

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

The outcome of back pain was not recovered.

The reporter did not assess the seriousness of back pain.

The reporter assessed the causality of back pain in relationship to Eligard and Eligard unspecified device as not related.

No further queries were raised.

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

Company Remarks (Sender's Comments) :

Evaluator comment (Tolmar): This case is regarding an elderly 90-year-old male patient who experienced back pain (Lower back pain/ waist pain) 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 event back pain was assessed as related as the contributory role of suspect drug Eligard cannot be ruled out considering known pharmacological profile of the drug. Back pain was assessed as not related to the device component of Eligard.

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) 14176A;UNK;UNK
Daily Dose	:	(45 milligram(s), 1 in 6 Month)
Route of Admin	:	1) Subcutaneous
Indications	:	1) Prostate cancer [10060862 - Prostate cancer]
Therapy Dates	:	1) From : 12/Jun/2021 To :Continuing
Action(s) Taken With Drug	:	Dose not changed

Causality

1) Lower back pain/ waist pain (Low back pain - 10024891, Back pain - 10003988)

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

Labeling :

Continuation Sheet for CIOMS report

1) Lower back pain/ waist 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) 14176A;UNK;UNK
Indications : 1) Prostate cancer [10060862 - Prostate cancer]
Action(s) Taken With Drug : Not applicable

Causality

1) Lower back pain/ waist pain (Low back pain - 10024891, Back pain - 10003988)
Causality as per reporter : Not Related
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) Lower back pain/ waist pain
CORE