SUSPECT ADVERSE REACTION REPORT

PA-Tolmar-TLM-2025-00447

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
J-R	PANAMA	16	May	1965	59	Male	20	Feb	2025

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

1) Low back pain (Low back ache (10024890), Back pain (10003988))
(20/Feb/2025 -) - Not Recovered/Not Resolved/Ongoing

Cont..

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)(15276CUY; Unk; Unk)

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)

1) (23/Oct/2023 - Ongoing)

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)

1)ERLEADA(APALUTAMIDE)

Cont..

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-2025-00447

24c. DATE RECEIVED BY MANUFACTURER

12/Apr/2025

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

DATE OF THIS REPORT

23/Apr/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 Panama was received by Adium via an email from the 'ASOFARMA A TU LADO' Patient Support Program (reference number: PA-ADIUM-PA-0037-20250412 (0)) on 12-Apr-2025 from a consumer (non-healthcare professional) regarding an adult 59-year-old male patient who experienced a non-serious event of 'low back pain" (Back pain) during Eligard (Leuprolide acetate) 45 milligram therapy for prostate cancer. The needle component of the constituent device was not identified in the report. The report was sent to Tolmar on 14-Apr-2025.

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

Concomitant medication included Erleada (apalutamide).

On 23-Oct-2023, the patient began receiving Eligard 45 mg lyophilized for injectable suspension, every 6 months via subcutaneous route for prostate cancer (Lot numbers: 15276CUY; Unk; Unk and Expiration dates: Aug-2026; Unk; Unk).

On 20-Feb-2025, the patient experienced lower back pain and indicated that he would undergo a pelvic abdominal CT scan on Apr-25. No further details were available.

Corrective treatment was unknown.

Relevant test results included:
On an unknown date in Apr-2025: CT scan: Unknown (Ref. range: Not provided).

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

The outcome of back pain was not resolved.

The reporter did not assess the seriousness of back pain.

The reporter did not provide the causality of back pain in relationship to Eligard and Eligard unspecified device.

No further queries were raised.

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

Company Remarks (Sender's Comments) :

Evaluator comment (Tolmar): This is regarding an adult 59-year-old male patient who experienced low back pain (back pain) during Eligard (Leuprolide acetate) 45 mg therapy for prostate cancer. Tolmar assessed the reported event as non-serious since it did not meet ICH seriousness criteria. The causality of event back pain was considered as related to suspect drug Eligard(not related to device) considering the known safety profile of drug.

Additional Information (Continuation...)

Lab Result :

Test Name	Test Date	Test Result	Normal Value
CT SCAN	/Apr/2025		

Test Result (Code) / Result Unstructured Data (free text) :

1) Test Name: CT SCAN

Result Unstructured Data (free text) : Unknown

Test Date: /Apr/2025

Lab Comments :

1) Test Name : CT SCAN

Lab Comments : Pelvic abdominal CT scan

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

Continuation Sheet for CIOMS report

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) 15276CUY; 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 : 23/Oct/2023 To :Continuing
Action(s) Taken With Drug	:	Dose not changed

Causality

1) Low back pain (Low back ache - 10024890, Back pain - 10003988)

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

Labeling :

1) Low back 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) 15276CUY; UNK; UNK
Indications	:	1) Prostate cancer [10060862 - Prostate cancer]
Action(s) Taken With Drug	:	Not applicable

Causality

1) Low back pain (Low back ache - 10024890, Back pain - 10003988)

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

Labeling :

1) Low back pain
CORE

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

Dosage Text :

Drug 1 :Eligard®

1) Expiration date -Aug-2026; Unk; Unk

Drug 2 :Eligard® Unspecified Device

1) Expiration date -Aug-2026; Unk; Unk

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

1). Drug	:	ERLEADA
Active Substance	:	1) APALUTAMIDE
Form Strength	:	
Indications	:	1) Product used for unknown indication [10070592 - Product used for unknown indication]