SUSPECT ADVERSE REACTION REPORT

PA-Tolmar-TLM-2025-05427

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
R ST F	PANAMA	28	Aug	1946	78	Male		Jun	2025

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

1) Right tibia fracture (Tibia fracture (10043827), Tibia fracture (10043827))
(/Jun/2025 -) - Recovering/Resolving
2) fall (Fall (10016173), Fall (10016173))
Unknown

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) (Injection)(UNK; UNK; 15276CUY)

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) (04/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
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	PA-Tolmar-TLM-2025-05427
24c. DATE RECEIVED BY MANUFACTURER: 01/Aug/2025	24d. REPORT SOURCE: ☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT: 06/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 Panama was received by Adium via the Patient Support Program "ASOFARMA A TU LADO" (Reference number: PA-ADIUM-PA-0084-20250801 (0)) on 01-Aug-2025 from a consumer (non-healthcare professional) regarding a 78-year-old elderly male patient who experienced a serious (medically significant) event of ‘‘Right tibia fracture" (tibia fracture) and "fall" (fall) during Eligard (Leuprolide acetate) 45 mg therapy for indication of prostate cancer. The needle component of the constituent device was not identified in the report. The report was sent to Tolmar on 04-Aug-2025.

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

Concomitant medications were unknown.

On 04-Feb-2025, the patient began receiving Eligard 45 mg, every 6 months, via subcutaneous route for the indication of prostate cancer (Lot numbers: UNK; UNK; 15276CUY and Expiration dates: UNK; UNK; Aug-2026).

On an unknown date in Jun-2025, the patient slipped because the floor was wet and that he suffered a fracture in his right tibia. Additionally, he mentioned that he did not require surgery.

No further information was provided.

Correction treatment was not reported.

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

The outcome of tibia fracture was recovering.

The outcome of fall was unknown.

The reporter did not assess the seriousness of tibia fracture and fall.

The reporter did not assess the causality of tibia fracture and fall in relationship to Eligard and Eligard unspecified device.

No further information is expected as consent to be contacted was not provided.

Listedness

Tibia fracture>Eligard>Unlisted as per CCDS>07-Nov-2024
Tibia fracture>Eligard>Unlisted as per USPI>Feb-2025
Tibia fracture>Eligard unspecified device>Unlisted as per USPI>Feb-2025
Tibia fracture>Eligard>Unlisted as per Canadian monograph>02-Apr-2025

Fall>Eligard>Unlisted as per CCDS>07-Nov-2024
Fall>Eligard>Unlisted as per USPI>Feb-2025
Fall>Eligard unspecified device>Unlisted as per USPI>Feb-2025
Fall>Eligard>Unlisted as per Canadian monograph>02-Apr-2025

Company Remarks (Sender's Comments) :

Evaluator comment (Tolmar): This is regarding 78-year-old elderly male patient who had Tibia fracture (Right tibia fracture) and Fall (Fall) 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 events tibia fracture and fall were assessed as not related to Eligard (drug and device) based on the etio-pathology of the events, known safety profile of the drug and inconsistency with drug properties.

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) UNK; UNK; 15276CUY
Daily Dose	: (45 milligram(s), 1 in 6 Month)
Route of Admin	: 1) Subcutaneous

Continuation Sheet for CIOMS report

Indications : 1) Prostate cancer [10060862 - Prostate cancer]
Therapy Dates : 1) From : 04/Feb/2025 To :Unknown
Action(s) Taken With Drug : Unknown

Causality

1) Right tibia fracture (Tibia fracture - 10043827, Tibia fracture - 10043827)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
2) fall (Fall - 10016173, Fall - 10016173)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) Right tibia fracture
CORE UnLabeled
2) fall
CORE UnLabeled

2) Drug : Eligard® Unspecified Device (Leuprolide acetate)
Active Substance : 1) Leuprolide acetate
Drug Characterization : Suspect
Form of Admin : 1) Injection
Lot Number : 1) UNK; UNK; 15276CUY
Indications : 1) Prostate cancer [10060862 - Prostate cancer]
Action(s) Taken With Drug : Not applicable

Causality

1) Right tibia fracture (Tibia fracture - 10043827, Tibia fracture - 10043827)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
2) fall (Fall - 10016173, Fall - 10016173)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) Right tibia fracture
CORE
2) fall
CORE

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

Dosage Text :

Drug 1 :Eligard®

1) Expiration dates: UNK; UNK; Aug-2026

Drug 2 :Eligard® Unspecified Device

1) Expiration dates: UNK; UNK; Aug-2026