SUSPECT ADVERSE REACTION REPORT

HN-Tolmar-TLM-2025-05727

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
PRIVACY	HONDURAS	16	Sep	1945	79	Female		Feb	2025

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

1) difficulty standing, no longer able to walk (Gait inability (10017581), Gait inability (10017581))
(/Feb/2025 -) - Not Recovered/Not Resolved/Ongoing
2) patient suffered a fall (Fall (10016173), Fall (10016173))
(11/Aug/2025 -) - Recovering/Resolving
3) dizziness (Dizziness (10013573), Dizziness (10013573))
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) (Injection)(Unknown)

Cont..

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

15. DAILY DOSE(S)

1) (45 milligram(s), 1 in 24 Week)

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 metastatic [10036909 - Prostate cancer metastatic]

18. THERAPY DATE(S) (from/to)	19. THERAPY DURATION
1) (03/Jul/2023 - 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 METASTATIC (10036909, Prostate cancer metastatic) (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
Anjan.Chatterjee@tolmar.comand+1-9702124900

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

24.REPORT NULLIFIED ☐ YES ☐ NO

24b. MFR CONTROL NO.

HN-Tolmar-TLM-2025-05727

24c. DATE RECEIVED BY MANUFACTURER

11/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 Brazil was received by Adium via "ASOFARMA A TU LADO" Patient Support Programme (Reference number: HN-ADIUM-HN-0316-20250811 (0)) on 11-Aug-2025 from a consumer (non-healthcare professional) regarding an elderly, 79-year-old male patient who experienced a serious (Disability/Permanent Damage) event of "difficulty standing no longer able to walk" (Gait inability) and non serious events of ''patient suffered a fall" (Fall) and "dizziness" (Dizziness) during Eligard (leuprolide acetate) 45 mg therapy for prostate cancer metastatic. The needle component of the constituent device was not identified in the report. The report was sent to Tolmar on 12-Aug-2025.

The patient's medical history was unknown and current conditions included metastatic prostate cancer, hypertension and diabetes mellitus.

Concomitant medications were not reported.

On 03-July-2023, the patient began receiving Eligard 45 mg, every 24 weeks, via subcutaneous route, for prostate cancer metastatic (Lot numbers and Expiration dates were not provided).

On an unknown date, the patient experienced dizziness.

On an unknown date in Feb-2025, the patient had difficulty standing and was no longer able to walk.

On 11-Aug-2025, the patient suffered a fall. In the morning, the patient attempted to walk and stand up but fell from a hammock. He was only able to stand with support and had to sit down quickly. He stated that his legs were not responding. No further information was available.

Corrective treatment was not reported.

Relevant test results included:
On an unknown date: PSA: 1.45 ng/ml (Ref. range: Not provided).

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

The outcome of dizziness and gait inability was not recovered and of fall was recovering.

The reporter assess the seriousness of gait inability as serious (Disability/Permanent Damage) whereas dizziness and fall as non serious.

The reporter assessed the causality of gait inability, dizziness and fall in relationship to Eligard and Eligard unspecified device as not related.

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

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

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

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

Company Remarks (Sender's Comments) :

Evaluator comment(Tolmar): This is regarding an elderly, 79-year-old male patient who experienced Gait inability(difficulty standing no longer able to walk), Fall (patient suffered a fall) and Dizziness (dizziness) during Eligard (leuprolide acetate) 45 mg therapy for prostate cancer metastatic. Tolmar assessed the event gait inability as serious (disability) as patient was only able to stand with support, not able to walk and based on its impact on patient's health(day to day activities) and events fall and dizziness were assessed as non-serious since they did not meet the ICH seriousness criteria. The causality of event gait inability and fall was assessed as not related to suspect Eligard(drug and device) as it could be attributed to patient's advancing age and age related changes whereas fall was secondary to gait inability. The causality of event dizziness was assessed as not related to suspect Eligard(drug and device) as it could be attributed to comorbid conditions such as hypertension and diabetes, elderly age and prostate cancer could be confounders for the event.

Continuation Sheet for CIOMS report

Additional Information (Continuation...)

Lab Result :

Test Name	Test Date	Test Result	Normal Value
PSA		1.45	

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) Unknown
Daily Dose : (45 milligram(s), 1 in 24 Week)
Route of Admin : 1) Subcutaneous
Indications : 1) Prostate cancer metastatic [10036909 - Prostate cancer metastatic]
Therapy Dates : 1) From : 03/Jul/2023 To :Continuing
Action(s) Taken With Drug : Dose not changed

Causality

1) difficulty standing, no longer able to walk (Gait inability - 10017581, Gait inability - 10017581)
Causality as per reporter : Not Related
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
2) patient suffered a fall (Fall - 10016173, Fall - 10016173)
Causality as per reporter : Not Related
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
3) dizziness (Dizziness - 10013573, Dizziness - 10013573)
Causality as per reporter : Not Related
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) difficulty standing, no longer able to walk
CORE UnLabeled
2) patient suffered a fall
CORE UnLabeled
3) dizziness
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 metastatic [10036909 - Prostate cancer metastatic]
Action(s) Taken With Drug : Not applicable

Causality

1) difficulty standing, no longer able to walk (Gait inability - 10017581, Gait inability - 10017581)
Causality as per reporter : Not Related
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
2) patient suffered a fall (Fall - 10016173, Fall - 10016173)
Causality as per reporter : Not Related
Causality as per Mfr : Not Related
DeChallenge : Not applicable

Continuation Sheet for CIOMS report

ReChallenge : Not Applicable

3) dizziness (Dizziness - 10013573, Dizziness - 10013573)
Causality as per reporter : Not Related
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) difficulty standing, no longer able to walk
CORE
2) patient suffered a fall
CORE
3) dizziness
CORE

23. OTHER RELEVANT HISTORY (Continuation...)

2) HIGH BLOOD PRESSURE (10020772 , Hypertension) (Continuing : YES)

3) DIABETES MELLITUS (10012601 , Diabetes mellitus) (Continuing : YES)