SUSPECT ADVERSE REACTION REPORT

GT-Tolmar-TLM-2025-04763

## 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 |
| CHCM | GUATEMALA | 16 | Aug | 1944 | 80 | Male | | May | 2025 |

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

1) Cannot walk (Unable to walk (10049278), Gait inability (10017581))
(/May/2025 - ) - Not Recovered/Not Resolved/Ongoing
2) Convulsion (Convulsion (10010904), Seizure (10039906))
(01/Jun/2025 - ) - Not Recovered/Not Resolved/Ongoing
3) two tumors, but it is not known whether they are benign, or malignant (Tumor (10084713), Neoplasm (10028980))
Unknown
4) Not hungry (Appetite lost (10003028), Decreased appetite (10061428))
(/May/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) (Injection)(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 |

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) (01/Mar/2013 - 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-2025-04763 |
| 24c. DATE RECEIVED BY MANUFACTURER: 16/Jul/2025 | 24d. REPORT SOURCE: ☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL |
| DATE OF THIS REPORT: 19/Jul/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 the Patient Support Program (reference number: GT-ADIUM-GT-0228-20250716 (0)) on 16-Jul-2025 from a consumer (non-healthcare professional) regarding an elderly 80-year-old male patient who experienced serious events of ''Cannot Walk'' (gait inability) (Disability/Permanent Damage), "Convulsion" (seizure) (medically significant) and 'two tumors, but it is not known whether they are benign, or malignant'' (Neoplasm), and non-serious event of '"not hungry" (Decreased appetite) 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 17-Jul-2025.

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

Concomitant medications were unknown.

On 01-Mar-2013, 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, the patient had an examination which revealed two tumors, but it is not known whether they are benign or malignant.

On an unknown date, at the end of Jul of unknown year, a brain MRI was performed, and the reports were given to the neurosurgery department.

On an unknown date in May-2025, the patient was in a wheelchair and unable to walk and had no appetite.

On 01-Jun-2025, the patient experienced convulsions and was taken to the emergency room where he was given anticonvulsants. No further details were provided.

Correction treatment included anticonvulsants for convulsions.

Relevant test results included:
On an unknown date: Laboratory test: found two tumors (Ref range: not provided).
On an unknown date in Jul of unknown year: MRI: 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 gait inability, seizures and decreased appetite was not recovered.

The outcome of neoplasm was unknown.

The reporter did not assess the seriousness of gait inability, seizures, neoplasm and decreased appetite.

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

The reporter did not assess the causality of neoplasm in relationship to Eligard and Eligard unspecified device

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

Listedness

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

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

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

Neoplasm>Eligard>Unlisted as per CCDS>07-Nov-2024
Neoplasm>Eligard>Unlisted as per USPI>Feb-2025
Neoplasm>Eligard>unspecified device>Unlisted as per USPI>Feb-2025

Continuation Sheet for CIOMS report

Neoplasm>Eligard>Unlisted as per Canadian monograph>02-Apr-2025

Company Remarks (Sender's Comments) :

Evaluator comment (Tolmar): This is regarding 80-year-old elderly male patient who had gait inability ('Cannot Walk"), seizure ("Convulsion") and neoplasm ('two tumors, but it is not known whether they are benign, or malignant"), and decreased appetite ("not hungry") during Eligard (Leuprolide acetate) 45 mg therapy for prostate cancer. Tolmar assessed the event gait inability as serious (disability) and events seizure and neoplasm as serious (IME). Tolmar assessed the event decreased appetite as non-serious since it does not meet the ICH seriousness criteria and is not an IME event. The reported events were assessed as not related to Eligard (drug and device) as the events are attributed to underlying prostate cancer and risk of probable metastasis/secondary tumor and elderly age.

Additional Information (Continuation...)

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

1) Test Name: EXAMINATION

Result Unstructured Data (free text) : Found two tumors

Test Date:

2) Test Name: MRI

Result Unstructured Data (free text) : unknown

Test Date:

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 6 Month) |
| Route of Admin | : | 1) Subcutaneous |
| Indications | : | 1) Prostate cancer [10060862 - Prostate cancer] |
| Therapy Dates | : | 1) From : 01/Mar/2013 To :Continuing |
| Action(s) Taken With Drug | : | Dose not changed |

Causality

1) Cannot walk (Unable to walk - 10049278, Gait inability - 10017581 )

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

2) Convulsion (Convulsion - 10010904, Seizure - 10039906 )

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

3) two tumors, but it is not known whether they are benign, or malignant (Tumor - 10084713, Neoplasm - 10028980 )

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

4) Not hungry (Appetite lost - 10003028, Decreased appetite - 10061428 )

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

Labeling :

| | |
|---|---|
| 1) Cannot walk | |
| CORE | UnLabeled |
| 2) Convulsion | |
| CORE | UnLabeled |
| 3) two tumors, but it is not known whether they are benign, or malignant | |
| CORE | UnLabeled |

Continuation Sheet for CIOMS report

4) Not hungry
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) Unknown
Indications : 1) Prostate cancer [10060862 - Prostate cancer]
Action(s) Taken With Drug : Not applicable

Causality

1) Cannot walk (Unable to walk - 10049278, Gait inability - 10017581 )
Causality as per reporter : Not Related
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

2) Convulsion (Convulsion - 10010904, Seizure - 10039906 )
Causality as per reporter : Not Related
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

3) two tumors, but it is not known whether they are benign, or malignant (Tumor - 10084713, Neoplasm - 10028980 )
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

4) Not hungry (Appetite lost - 10003028, Decreased appetite - 10061428 )
Causality as per reporter : Not Related
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) Cannot walk
CORE
2) Convulsion
CORE
3) two tumors, but it is not known whether they are benign, or malignant
CORE
4) Not hungry
CORE