CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

DO-Tolmar-TLM-2025-04796

## I. REACTION INFORMATION

| 1. PATIENT INITIALS (first, last) | 1a. COUNTRY | 2. DATE OF BIRTH | | | 2a. AGE | 3. SEX | 4-6 REACTION ONSET | | |
|---|---|---|---|---|---|---|---|---|---|
| | | Day | Month | Year | Years | | Day | Month | Year |
| T-A | DOMINICAN Cont.. | 11 | Jan | 1951 | | Male | | | |

**8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION**

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

1) DEATH (Death (10011906), Death (10011906))
Fatal

- [x] 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 [x] 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 [x] 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) (06/Nov/2024 - ) | |

## 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 | DO-Tolmar-TLM-2025-04796 |
| 24c. DATE RECEIVED BY MANUFACTURER: 06/Aug/2025 | 24d. REPORT SOURCE: [x] STUDY [ ] LITERATURE [ ] HEALTH PROFESSIONAL |
| DATE OF THIS REPORT: 12/Aug/2025 | 25a. REPORT TYPE: [ ] INITIAL [x] FOLLOWUP |

= Continuation attached sheet(s)..

Continuation Sheet for CIOMS report

1a. COUNTRY

DOMINICAN REPUBLIC

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

Event Description :

This study report from Dominican Republic was received by Adium Pharma S.A via an electronic form through the Jazz Safety tool of the "ASOFARMA A TU LADO" Patient Support Program (reference number: DO-ADIUM-DO-0079-20250717) on 17-Jul-2025, from a reporter (non-healthcare professional) regarding an elderly male patient experienced serious (death) event of "death" (death) 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 18-Jul-2025.

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

Concomitant medications were unknown.

On 06-Nov-2024, the patient began receiving Eligard 45 mg every 6 months via subcutaneous route for prostate cancer (Lot numbers and Expiration dates were unknown).

On an unknown date, the patient died due to unknown cause of death. The patient was 74 years old at the time of his death. It was unknown if an autopsy was performed. No further details were provided.

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

The outcome of death was fatal.

The reporter assesses the seriousness of death as serious.

The reporter provided the causality of death in relationship to Eligard and Eligard Unspecified Device as not related.

No further information is expected as the reporter does not consent to be contacted for follow up.

On 06-Aug-2025, the follow up information was received by Adium via "ASOFARMA A TU LADO" Patient Support Program (reference number: DO-ADIUM-DO-0079-20250717 (1)) from a consumer (non-healthcare professional) and sent to Tolmar on 07-Aug-2025. New information included: The reporter mentioned that the patient passed away 5 months ago. No further details were provided.

No further information is expected as the reporter does not consent to be contacted for follow up.

Listedness:

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

Company Remarks (Sender's Comments) :

Evaluator comment (Tolmar): This is regarding an elderly male patient experienced serious (death) event of "death" (death) during Eligard (leuprolide acetate) 45 mg therapy for prostate cancer. Tolmar assessed the event of death as serious (fatal). Due to limited information regarding nature and cause of death, autopsy details, medical history and concomitant medications, causality for event death is not assessable with Eligard (drug) and not related with device component. Underlying cancer is a strong confounder in the case.

FU-Causality of the event death is retained as per previous assessment.

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 |

Continuation Sheet for CIOMS report

| | | |
|---|---|---|
| Indications | : | 1) prostate cancer [10060862 - Prostate cancer] |
| Therapy Dates | : | 1) From : 06/Nov/2024 To :Not applicable |
| Action(s) Taken With Drug | : | Not applicable |

Causality

1) DEATH (Death - 10011906, Death - 10011906 )

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

Labeling :

1) DEATH
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) DEATH (Death - 10011906, Death - 10011906 )

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

Labeling :

1) DEATH
CORE