SUSPECT ADVERSE REACTION REPORT

DO-Tolmar-TLM-2025-01618

## I. REACTION INFORMATION

| 1. PATIENT INITIALS (first, last) | 1a. COUNTRY | 2. DATE OF BIRTH | | | 2a. AGE | 3. SEX | 4-6 REACTION ONSET | | | 8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Day | Month | Year | Years | | Day | Month | Year | |
| JDR | DOMINICAN Cont.. | 20 | Nov | 1952 | 72 | Male | | | | ☐ PATIENT DIED<br>☐ LIFE THREATENING<br>☐ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION<br>☐ RESULTS IN PERSISTENCE OR SIGNIFICANT DISABILITY/INCAPACITY<br>☐ CONGENITAL ANOMALY<br>☐ OTHER MEDICALLY IMPORTANT CONDITION |

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

1) Heat (Feeling hot (10016334), Feeling hot (10016334))
Not Recovered/Not Resolved/Ongoing

Cont..

## 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 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) (25/Mar/2025 - Ongoing) | |

## III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

1)OTHER THERAPEUTIC PRODUCTS(CHEMOTHERAPY)

Cont..

23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

1) KIDNEY TRANSPLANT (10023438, Kidney transplant) (//2010 - ) (Continuing: No)

Cont..

## 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 | 24b. MFR CONTROL NO. |
|---|---|
| ☐ YES ☐ NO | DO-Tolmar-TLM-2025-01618 |
| 24c. DATE RECEIVED BY MANUFACTURER<br>08/May/2025 | 24d. REPORT SOURCE<br>☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL |
| DATE OF THIS REPORT<br>19/May/2025 | 25a. REPORT TYPE<br>☑ INITIAL ☐ 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 via the 'ASOFARMA A TU LADO' Patient Support Program (reference number: DO-ADIUM-DO-0033-20250508) on 08-May-2025 from a consumer (non-healthcare professional) regarding an elderly 72-year-old male patient who experienced a non-serious event of 'Heat' (Feeling hot) 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 12-May-2025.

The patient's medical history included renal transplant, gallbladder operation and current condition included prostate cancer, blood pressure abnormal, blood glucose abnormal).

Concomitant medication included chemotherapy.

On 25-Mar-2025, 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 went under 44 chemotherapy sessions, which he was still continuing, he also mentioned that due to Eligard the patient was experiencing heat that he would not like to feel. It was informed that the patient may experience heat for another 15 days, but that Eligard will protect him over the next 6 months. The patient also consulted several doctors doctor, such as urologist and nephrologist. Additionally, the patient was suffering from many illnesses such as kidney transplant, he had recent surgery of gallbladder attached to hernia, and suffering from high blood pressure and sugar.

On 23-Dec-2024, the patient had a biopsy. Further details were not provided.

Corrective treatment was not reported.

Relevant test results included:
On 23-Dec-2024: Biopsy: 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 feeling hot was not recovered.

The reporter did not assess the seriousness of feeling hot.

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

No further queries were raised.

Listedness

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

Company Remarks (Sender's Comments) :

Evaluator comment (Tolmar): This is regarding an elderly 72-year-old male patient who experienced Feeling hot (Heat) 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 event was assessed as related to Eligard (drug) considering the time to onset of event however, confounded by concomitant chemotherapy. Tolmar assessed the event feeling hot as not related to device component of Eligard.

Additional Information (Continuation...)

Lab Result :

| Test Name | Test Date | Test Result | Normal Value |
|---|---|---|---|
| BIOPSY | 23/Dec/2024 | | |

Continuation Sheet for CIOMS report

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

1) Test Name: BIOPSY

Result Unstructured Data (free text) : Unknown

Test Date: 23/Dec/2024

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 : 25/Mar/2025 To :Continuing |
| Action(s) Taken With Drug | : | Dose not changed |

Causality

1) Heat (Feeling hot - 10016334, Feeling hot - 10016334 )

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

Labeling :

1) Heat

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 |
| Route of Admin | : | 1) Subcutaneous |
| Indications | : | 1) prostate cancer [10060862 - Prostate cancer] |
| Action(s) Taken With Drug | : | Not applicable |

Causality

1) Heat (Feeling hot - 10016334, Feeling hot - 10016334 )

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

Labeling :

1) Heat

CORE

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

| | | |
|---|---|---|
| 1). Drug | : | OTHER THERAPEUTIC PRODUCTS |
| Active Substance | : | 1) CHEMOTHERAPY |
| Form Strength | : | |
| Indications | : | 1) Prostate cancer [10060862 - Prostate cancer] |

23. OTHER RELEVANT HISTORY (Continuation...)

2) PROSTATE CANCER (10060862 , Prostate cancer) (Continuing : YES )

3) SUGAR (10005554 , Blood glucose abnormal) (Continuing : YES )

4) GALLBLADDER SURGERY IN CONJUNCTION WITH A HERNIA (10019909 , Hernia) (Continuing : NO )

5) BLOOD PRESSURE (10005728 , Blood pressure abnormal) (Continuing : YES )

Continuation Sheet for CIOMS report

6) GALLBLADDER SURGERY IN CONJUNCTION WITH A HERNIA (10061962 , Gallbladder operation) (Continuing : Unknown)