SUSPECT ADVERSE REACTION REPORT

DO-Tolmar-TLM-2025-01817

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	
PRIVACY	DOMINICAN Cont..	19	Oct	1949	75	Male			2025	

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

1) Bilateral breast swelling (Breast swelling (10006312), Breast swelling (10006312))
(//2025 -) - Recovered/Resolved
2) Rash/rash on his upper limbs (Localised rash (10062704), Rash (10037844))
(//2025 -) - Recovered/Resolved

- ☐ 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) (22.5 Milligram, Injection)(15109CUY;UNK;UNK)

Cont..

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

15. DAILY DOSE(S)

1) (22.5 milligram(s), 1 in 3 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
(-Feb-2025 - Ongoing)	

III. CONCOMITANT DRUG(S) AND HISTORY

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

1)HYDROCORTISONE(HYDROCORTISONE)

Cont..

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

1) PROSTATE CANCER (10060862, Prostate cancer) (/Feb/2025 -) (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
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-2025-01817
24c. DATE RECEIVED BY MANUFACTURER: 21/May/2025	24d. REPORT SOURCE: ☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT: 29/May/2025	25a. REPORT TYPE: ☐ 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 Patient Support Program (reference number: DO-ADIUM-DO-0037-20250513) on 13-May-2025 from a consumer (non-healthcare professional) regarding an elderly 75-year-old male patient who experienced non serious events of "rash/rash on his upper limbs" (rash) and "bilateral breast swelling" (breast swelling) during Eligard (leuprolide) 22.5 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 14-May-2025.

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

Concomitant medications were unknown.

On an unknown date in Feb-2025, the patient began receiving Eligard 22.5 mg, every 3 months via subcutaneous route for prostate cancer (Lot numbers; 15109CUY; UNK; UNK and Expiration dates; May-2026; UNK; UNK).

On an unknown date in 2025, the patient experienced rash on his upper limbs which was moderate in nature. Additionally, he also had mild bilateral breast swelling which disappeared without further action.

Corrective treatment included topical hydrocortisone cream for rash.

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

The outcome of rash and breast swelling was recovered.

The reporter did not assess the seriousness or causality of rash, breast swelling in relationship to Eligard and Eligard unspecified device.

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

On 21-May-2025, follow-up information from Dominican Republic was received by Adium via Patient Support Program (reference number: DO-ADIUM-DO-0037-20250513(1)) from a consumer (non-healthcare professional) after a local review, regarding an elderly 75-year-old male patient. The report was sent to Tolmar on 21-May-2025. New information included: Reporter causality updated.

The reporter provided the causal relationship between the adverse event(s) and the drug(s).

The reporter assessed the causality of breast swelling in relationship to Eligard and Eligard unspecified device as related and with event rash as not related.

Listedness:
Rash>Eligard>Unlisted as per CCDS>07-Nov-2024
Rash>Eligard>Unlisted as per USPI>Feb-2025
Rash>Eligard unspecified device>Unlisted as per USPI>Feb-2025
Rash>Eligard>listed as per Canadian monograph>02-Apr-2025

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

Company Remarks (Sender's Comments) :

Evaluator comment (Tolmar): This is regarding an elderly 75-year-old male patient who developed rash and breast swelling during Eligard (leuprolide acetate) 22.5 mg therapy for prostate cancer. Tolmar assessed the reported events as non-serious since they did not meet the ICH seriousness criteria and are not IME events. The reported events were assessed as related to Eligard (drug) based on plausible temporality and as not related to device.

14.SUSPECT DRUG(S) (Continuation...)

Product-Reaction Level

1) Drug	:	Eligard® (Leuprolide acetate)
Active Substance	:	1) Leuprolide acetate
Drug Characterization	:	Suspect

Continuation Sheet for CIOMS report

Form Strength : 1) 22.5 Milligram
Form of Admin : 1) Injection
Lot Number : 1) 15109CUY;UNK;UNK
Daily Dose : (22.5 milligram(s), 1 in 3 Month)
Route of Admin : 1) Subcutaneous
Indications : 1) Prostate cancer [10060862 - Prostate cancer]
Action(s) Taken With Drug : Dose not changed

Causality

1) Bilateral breast swelling (Breast swelling - 10006312, Breast swelling - 10006312)
Causality as per reporter : Related
Causality as per Mfr : Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
2) Rash/rash on his upper limbs (Localised rash - 10062704, Rash - 10037844)
Causality as per reporter : Not Related
Causality as per Mfr : Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) Bilateral breast swelling
CORE UnLabeled
2) Rash/rash on his upper limbs
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) 15109CUY;UNK;UNK
Indications : 1) Prostate cancer [10060862 - Prostate cancer]
Action(s) Taken With Drug : Not applicable

Causality

1) Bilateral breast swelling (Breast swelling - 10006312, Breast swelling - 10006312)
Causality as per reporter : Related
Causality as per Mfr : Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
2) Rash/rash on his upper limbs (Localised rash - 10062704, Rash - 10037844)
Causality as per reporter : Not Related
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) Bilateral breast swelling
CORE
2) Rash/rash on his upper limbs
CORE

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

Dosage Text :

Drug 1 :Eligard®

1) Expiration date: May-26;UNK;UNK ELIGARD 22.5 MG x 1 LIO x 2 JER

Drug 2 :Eligard® Unspecified Device

1) Expiration date: May-26;UNK;UNK

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

1). Drug : HYDROCORTISONE
Active Substance : 1) HYDROCORTISONE
Form Strength :

Continuation Sheet for CIOMS report

Indications	:	1) Rash [10062704 - Localised rash]