SUSPECT ADVERSE REACTION REPORT

GT-Tolmar-TLM-2025-01231

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
CGSC	GUATEMALA	17	Jul	1955	69	Male	28	Apr	2025

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

1) lump or swelling on the right side of her jaw (Osteitis (10031149), Osteitis (10031149)) (28/Apr/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)(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
2) (45 milligram(s), 1 in 6 Month)	2) 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) (04/Sep/2024 - Ongoing)	

III. CONCOMITANT DRUG(S) AND HISTORY

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

1)TEOPRIN(BICALUTAMIDE)(/Jun/2023 - 15/Mar/2025)

Cont..

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

1) PROSTATE CANCER (10060862, Prostate cancer) (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
debbie.maierhofer@tolmar.comand+1-4129158447

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

24.REPORT NULLIFIED ☐ YES ☐ NO

24b. MFR CONTROL NO.

GT-Tolmar-TLM-2025-01231

24c. DATE RECEIVED BY MANUFACTURER

28/Apr/2025

24d. REPORT SOURCE ☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL

DATE OF THIS REPORT

08/May/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 (reference number: GT-ADIUM-GT-0139-20250428) on 28-Apr-2025 and 29-Apr-2025 from a consumer (non-health care professional) (patient' daughter) regarding an elderly 69-year-old male patient who developed a "lump or swelling on the right side of her jaw" (osteitis) during Eligard (leuprolide acetate) 45 mg therapy for prostate cancer. The report was sent to Tolmar on 29-Apr-2025.

The patient's medical history included tooth extraction and current condition included prostate cancer.

Concomitant medication included Teoprin (bicalutamide).

On 04-Sep-2024, 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 06-Mar-2024, the patient received Eligard 45 mg, every 6 months via subcutaneous route for prostate cancer (Lot numbers and Expiration dates were not provided).

On 18-Oct-2024 and 24-Mar-2025, the patient had a bone scan, and the result came out well. However, the patient's daughter upon validating the results of these exams stated that the patient had a dental prosthesis, but he does not have that, because the only thing he had was the space that was left when the tooth extraction was performed.

On 27-Apr-2025, the patient had no lump or inflammation.

On 28-Apr-2025, the patient developed a lump or swelling on the right side of his jaw, but it was not caused by a blow. However, he did not take any medication and did not consult with a doctor.

Corrective treatment was not reported.

Relevant test included:

On 18-Oct-2024 and 24-Mar-2025: bone scan: Results of exam came out well (Reference range: not provided)

On 04-Mar-2025: PSA: 0.003 ng/ml (Reference range: not provided)

On 09-Jan-2025: PSA: 0.004 ng/ml (Reference range: not provided)

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

The outcome of osteitis was not resolved.

The reporter did not assess the seriousness of osteitis.

The reporter did not provide the causality of osteitis to Eligard and Eligard unspecified device.

No follow-up queries raised.

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

Company Remarks (Sender's Comments) :

Evaluator comment (Tolmar): This is regarding an elderly 69-year-old male patient who developed osteitis (lump or swelling on the right side of her jaw) during Eligard (leuprolide acetate) 45 mg therapy for prostate cancer. Tolmar assessed the reported event as non-serious since it did not meet the ICH seriousness criteria. The causality of the event osteitis was assessed as not related to suspect Eligard(drug and device) considering the nature of the event, inconsistency with the safety profile of the drug and history of tooth extraction could be a risk factor.

Additional Information (Continuation...)

Lab Result :

Test Name	Test Date	Test Result	Normal Value

Continuation Sheet for CIOMS report

BONE SCAN	18/Oct/2024		
BONE SCAN	24/Mar/2025		
PSA TEST	09/Jan/2025	0.004 nanogram per millliiter	
PSA TEST	04/Mar/2025	0.003 nanogram per millliiter	

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

1) Test Name: BONE SCAN

Result Unstructured Data (free text) : Results of exam came out well
Test Date: 18/Oct/2024

2) Test Name: BONE SCAN

Result Unstructured Data (free text) : Results of exam came out well
Test Date: 24/Mar/2025

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
2) Injection
Lot Number : 1) Unknown
2) Unknown
Daily Dose : (45 milligram(s), 1 in 6 Month)
(45 milligram(s), 1 in 6 Month)
Route of Admin : 1) Subcutaneous
2) Subcutaneous
Indications : 1) Prostate cancer [10060862 - Prostate cancer]
Therapy Dates : 1) From : 04/Sep/2024 To :Continuing
2) From : 05/Mar/2025 To :Continuing
Action(s) Taken With Drug : Dose not changed

Causality

1) lump or swelling on the right side of her jaw (Osteitis - 10031149, Osteitis - 10031149)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) lump or swelling on the right side of her jaw
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) lump or swelling on the right side of her jaw (Osteitis - 10031149, Osteitis - 10031149)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

Continuation Sheet for CIOMS report

1) lump or swelling on the right side of her jaw
CORE

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

Dosage Text :

Drug 1 :Eligard®

2) ELIGARD 45 MG x 1 LIO x 1 JER

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

1). Drug	:	TEOPRIN
Active Substance	:	1) BICALUTAMIDE
Form Strength	:	
Daily Dose	:	1) (50 milligram(s))
Indications	:	1) Prostate cancer [10060862 - Prostate cancer]
Therapy Dates	:	1) From : /Jun/2023 To : 15/Mar/2025

23. OTHER RELEVANT HISTORY (Continuation...)

2) TOOTH EXTRACTION (10062132 , Tooth extraction) (Continuing : NO)