SUSPECT ADVERSE REACTION REPORT

GT-Tolmar-TLM-2025-03904

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE Years	3. SEX	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year			Day	Month	Year	
AEMB	GUATEMALA	24	Dec	1957	67	Male	10	Jun	2025	

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

1) Constipation (Constipation (10010774), Constipation (10010774))
(10/Jun/2025 -) - Not Recovered/Not Resolved/Ongoing
2) Anal pain (Anal pain (10002167), Proctalgia (10036772))
(12/Jun/2025 -) - Not Recovered/Not Resolved/Ongoing

- ☐ 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)

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) (07/Jun/2025 - 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-2025-03904
24c. DATE RECEIVED BY MANUFACTURER: 19/Jun/2025	24d. REPORT SOURCE: ☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT: 25/Jun/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 'ASOFARMA A TU LADO' Patient Support Program (reference number: GT-ADIUM-GT-0196-2025061) on 19-Jun-2025 from a consumer (non-healthcare professional) regarding a 67-year-old male patient who experienced non-serious events of ''Anal pain" (Proctalgia) and "Constipation" (Constipation) during Eligard (Leuprolide acetate) 45 milligram therapy for prostate cancer. The needle component of the constituent device was not identified in the report. The report was sent to Tolmar on 20-Jun-2025.

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

Concomitant medications were unknown.

On 07-Jun-2025, the patient began receiving Eligard 45 mg, every 6 months, via subcutaneous route for the indication of prostate cancer (Lot numbers and Expiration dates were not provided).

On an unknown date, the patient experienced events of ''Anal pain" (Proctalgia) and "Constipation" (Constipation). However, the patient continued with the medication.

Correction treatment for anal pain was not reported, and constipation required treatment (details unknown).

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

The outcome of proctalgia and constipation was not recovered.

The reporter did not assess the seriousness of proctalgia and constipation.

The reporter assessed the causality of proctalgia and constipation in relationship to Eligard and Eligard unspecified device as not related.

No further queries were raised.

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

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

Company Remarks (Sender's Comments) :

Evaluator comment (Tolmar): This is regarding a 67-year-old male patient who experienced proctalgia (Anal pain) and constipation (Constipation) during Eligard (Leuprolide acetate) 45 milligram therapy for prostate cancer. Tolmar assessed the reported events as non-serious since they did not meet the ICH seriousness criteria. The causality of events proctalgia and constipation was assessed as related to suspect Eligard(drug) considering close temporality and elderly age could be risk factor for the event and both the events are not related to drug component of Eligard.

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 : 07/Jun/2025 To :Continuing
Action(s) Taken With Drug	:	Dose not changed

Causality

1) Constipation (Constipation - 10010774, Constipation - 10010774)

Continuation Sheet for CIOMS report

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

2) Anal pain (Anal pain - 10002167, Proctalgia - 10036772)
Causality as per reporter : Not Related
Causality as per Mfr : Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) Constipation
CORE Labeled
2) Anal pain
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) Constipation (Constipation - 10010774, Constipation - 10010774)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

2) Anal pain (Anal pain - 10002167, Proctalgia - 10036772)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) Constipation
CORE
2) Anal pain
CORE