SUSPECT ADVERSE REACTION REPORT

GT-TOLMAR, INC.-25GT057669

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
AAMA	GUATEMALA	17	Oct	1937	87	Male	13	May	2024

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

1) Pain and inflammation in the area of injection (Injection site inflammation (10022078), Injection site inflammation (10022078))
(12/Mar/2025 -) - Not Recovered/Not Resolved/Ongoing
2) Leg pain (Leg pain (10024130), Pain in extremity (10033425))
(13/May/2024 -) - Recovering/Resolving
3) Defenses are lowered (Immune system disorder (10021425), Immune system disorder (10021425))
(13/May/2024 -) - Recovering/Resolving
4) Suspension of treatment (Therapy cessation (10065154), Therapy cessation (10065154))
(/Mar/2025 -) - Unknown

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) (22.5 Milligram, Injection)(Unknown)

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
1) (13/May/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) (/Jan/2024 -) (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

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, INC.-25GT057669
24c. DATE RECEIVED BY MANUFACTURER: 26/Jun/2025	24d. REPORT SOURCE: ☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT: 07/Jul/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...)

5) Pain and inflammation in the area of injection (Injection site pain (10022086), Injection site pain (10022086)(12/Mar/2025 -) - Not Recovered/Not Resolved/Ongoing)

6) Tiredness (Tiredness (10043890), Fatigue (10016256)(13/May/2025 -) - Recovering/Resolving)

Event Description :

This Study report from GUATEMALA was received by Adium via Patient Support Program (reference number: GT-ADIUM-GT-0090-20250317) on 17-MAR-2025 from a Consumer/Other Non-Health Prof regarding elderly 87 years old male patient who experienced pain and inflammation in the area of injection (Injection site pain), (Injection site inflammation) during Eligard (Leuprolide acetate) 22.5 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 18-MAR-2025.

The patient's medical history and current conditions included prostate cancer.

Concomitant medications were not reported.

On 13-MAY-2024, the patient began receiving Eligard 22.5 milligram, q 3 month via subcutaneous use for prostate cancer (Lot number and Expiration date: not reported). On 12-MAR-2025, 10 months after the most recent dose of Eligard, the patient experienced pain and inflammation in the area of injection but still continues with the symptoms. Corrective treatment was not reported. Action taken with Eligard in response to the events was dose not changed. De-challenge and re-challenge were not applicable. The outcome of Injection site pain was not recovered/not resolved. The outcome of Injection site inflammation was not recovered/not resolved.

The reporter did not assess the seriousness of the events and assessed the causality in relationship to Eligard as not reported.

On 26-Jun-2025, the follow up from Guatemala was received by Adium via Patient Support Program "ASOFARMA A TU LADO" (reference number: GT-ADIUM-GT-0090-20250317) and sent to Tolmar on 27-Jun-2025. New information included: Updated the start date of Prostate cancer (Jan-2024), action taken of Eligard (drug withdrawn), dechallenge (positive), added new non-serious events of "Tiredness" (fatigue), "Leg pain" (Pain in extremity), "Defenses are lowered" (Immune system disorder) and "Suspension of treatment" (Therapy cessation) and narrative was updated.

The patient's medical history and current conditions included prostate cancer from Jan-2024.

On an unknown date in Mar-2025, the patient's therapy was suspended.

On 13-May-2024, the patient experienced tiredness, leg pain and the defenses were lowered. No further information was provided.

Corrective treatment was not reported.

Action taken with Eligard in response to events fatigue, pain in extremity and immune system disorder was drug withdrawn. De-challenge was positive and Re-challenge was not applicable.

The outcome of the events fatigue, pain in extremity and immune system disorder was resolving.

The outcome of the event therapy cessation was unknown.

The reporter did not assess the seriousness of the events fatigue, pain in extremity, immune system disorder and therapy cessation.

The reporter provided the causality of the events fatigue, pain in extremity, immune system disorder and therapy cessation as related in relation to Eligard and Eligard Unspecified Device.

No further query was raised.

Listedness of the events Injection site pain and Injection site inflammation is retained as per previous assessment.

Pain in extremity>Eligard>Unlisted as per CCDS>07-Nov-2024
Pain in extremity>Eligard>Unlisted as per USPI>Feb-2025
Pain in extremity>Eligard>unspecified device>Unlisted as per USPI>Feb-2025
Pain in extremity>Eligard>Unlisted as per Canadian monograph>02-Apr-2025

Immune system disorder >Eligard>Unlisted as per CCDS>07-Nov-2024
Immune system disorder >Eligard>Unlisted as per USPI>Feb-2025
Immune system disorder >Eligard>unspecified device>Unlisted as per USPI>Feb-2025
Immune system disorder >Eligard>Unlisted as per Canadian monograph>02-Apr-2025

Therapy cessation>Eligard>Unlisted as per CCDS>07-Nov-2024
Therapy cessation>Eligard>Unlisted as per USPI>Feb-2025
Therapy cessation>Eligard>unspecified device>Unlisted as per USPI>Feb-2025

Continuation Sheet for CIOMS report

Therapy cessation>Eligard>Unlisted as per Canadian monograph>02-Apr-2025

Fatigue>Eligard>listed as per CCDS>07-Nov-2024
Fatigue>Eligard>listed as per USPI>Feb-2025
Fatigue>Eligard>unspecified device>listed as per USPI>Feb-2025
Fatigue>Eligard>listed as per Canadian monograph>02-Apr-2025

Company Remarks (Sender's Comments) :

Evaluator comment (Tolmar): This is regarding 87-year-old elderly male patient who had pain in extremity (Leg pain), immune system disorder (Defenses are lowered), therapy cessation (Suspension of treatment) and fatigue (Tiredness) during Eligard 22.5 mg 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 causality of the reported events pain in extremity, immune system disorder and fatigue were assessed as related to Eligard (drug and device) based on the known safety profile of the drug. However, the role of advanced age of the patient and underlying prostate cancer cannot be ruled out. The causality of the reported event therapy cessation was assessed as not related to Eligard (drug and device) as the event occurred with the product due to human action, rather due to the drug.

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

Product-Reaction Level

1) Drug	:	Eligard® (Leuprolide acetate)
Active Substance	:	1) Leuprolide acetate
Drug Characterization	:	Suspect
Form Strength	:	1) 22.5 Milligram
Form of Admin	:	1) Injection
Lot Number	:	1) Unknown
Daily Dose	:	(22.5 milligram(s), 1 in 3 Month)
Route of Admin	:	1) Subcutaneous
Indications	:	1) Prostate cancer [10060862 - Prostate cancer]
Therapy Dates	:	1) From : 13/May/2024 To :
Action(s) Taken With Drug	:	Drug withdrawn

Causality

1) Pain and inflammation in the area of injection (Injection site inflammation - 10022078, Injection site inflammation - 10022078)

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

2) Leg pain (Leg pain - 10024130, Pain in extremity - 10033425)

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

3) Defenses are lowered (Immune system disorder - 10021425, Immune system disorder - 10021425)

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

4) Suspension of treatment (Therapy cessation - 10065154, Therapy cessation - 10065154)

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

5) Pain and inflammation in the area of injection (Injection site pain - 10022086, Injection site pain - 10022086)

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

6) Tiredness (Tiredness - 10043890, Fatigue - 10016256)

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

Labeling :

1) Pain and inflammation in the area of injection

Continuation Sheet for CIOMS report

CORE	UnLabeled
2) Leg pain	
CORE	UnLabeled
3) Defenses are lowered	
CORE	UnLabeled
4) Suspension of treatment	
CORE	UnLabeled
5) Pain and inflammation in the area of injection	
CORE	Labeled
6) Tiredness	
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) Unknown
Route of Admin	:	1) Subcutaneous
Indications	:	1) Prostate cancer [10060862 - Prostate cancer]
Therapy Dates	:	1) From : 13/May/2024 To :Not applicable
Action(s) Taken With Drug	:	Not applicable

Causality

1) Pain and inflammation in the area of injection (Injection site inflammation - 10022078, Injection site inflammation - 10022078)

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

2) Leg pain (Leg pain - 10024130, Pain in extremity - 10033425)

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

3) Defenses are lowered (Immune system disorder - 10021425, Immune system disorder - 10021425)

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

4) Suspension of treatment (Therapy cessation - 10065154, Therapy cessation - 10065154)

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

5) Pain and inflammation in the area of injection (Injection site pain - 10022086, Injection site pain - 10022086)

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

6) Tiredness (Tiredness - 10043890, Fatigue - 10016256)

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

Labeling :

1) Pain and inflammation in the area of injection
CORE
2) Leg pain
CORE
3) Defenses are lowered
CORE
4) Suspension of treatment
CORE
5) Pain and inflammation in the area of injection
CORE
6) Tiredness
CORE

Continuation Sheet for CIOMS report

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

Dosage Text :

Drug 1 :Eligard®

1) 22.5 milligram, q 3 month

Drug 2 :Eligard® Unspecified Device

1) UNK