SUSPECT ADVERSE REACTION REPORT

PA-Tolmar-TLM-2025-00966

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
G-P	PANAMA	02	Jul	1942	82	Male	15	Apr	2025

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

1) Knee pain due to wear (Arthralgia (10003239), Arthralgia (10003239))
(15/Apr/2025 -) - Not Recovered/Not Resolved/Ongoing

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)(15276CUY; Unk; Unk)

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) (19/Jun/2019 - 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
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	PA-Tolmar-TLM-2025-00966
24c. DATE RECEIVED BY MANUFACTURER	24d. REPORT SOURCE
21/Apr/2025	☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT	25a. REPORT TYPE
03/May/2025	☑ 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 Panama was received via Adium (reference number: PA-ADIUM-PA-0040-2025042) on 21-Apr-2025 from a consumer (non-healthcare professional) regarding an elderly 82-year-old male patient who had a "Knee pain due to wear" (Arthralgia) 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 22-Apr-2025.

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

Concomitant medications were unknown.

On 19-Jun-2019, the patient began receiving Eligard 45 mg, every 6 months, via subcutaneous route for prostate cancer (Lot number: 15276CUY, UNK, UNK and Expiration dates: Aug-2026, UNK, UNK).

On 15-Apr-2025, the patient experienced severe knee pain due to wear. No further details were available.

Corrective treatment was unknown.

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

The outcome of arthralgia was not recovered.

The reporter did not assess the seriousness of arthralgia.

The reporter did not assess the causality of arthralgia in relationship to Eligard and Eligard unspecified device.

No follow up queries were raised.

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

Company Remarks (Sender's Comments) :

Evaluator comment (Tolmar): This is regarding an elderly 82-year-old male patient who experienced arthralgia (Knee pain due to wear) during Eligard (Leuprolide acetate) 45 mg therapy for prostate cancer. Tolmar assessed the reported event as non-serious since it did not meet ICH seriousness criteria. The causality of event arthralgia was considered as not related to suspect Eligard(drug and device) as the event was due to wear and tear as per available information and elderly age of the patient could be a risk factor for the event.

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) 15276CUY; Unk; Unk
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 : 19/Jun/2019 To :Continuing
Action(s) Taken With Drug	:	Dose not changed

Causality

1) Knee pain due to wear (Arthralgia - 10003239, Arthralgia - 10003239)

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) Knee pain due to wear
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) 15276CUY; Unk; Unk
Indications : 1) Prostate cancer [10060862 - Prostate cancer]
Action(s) Taken With Drug : Not applicable

Causality

1) Knee pain due to wear (Arthralgia - 10003239, Arthralgia - 10003239)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) Knee pain due to wear
CORE