

SUSPECT ADVERSE REACTION REPORT	
DO-Tolmar-TLM-2025-04202	

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 <input type="checkbox"/> PATIENT DIED <input type="checkbox"/> LIFE THREATENING <input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION <input type="checkbox"/> RESULTS IN PERSISTENCE OR SIGNIFICANT DISABILITY/INCAPACITY <input type="checkbox"/> CONGENITAL ANOMALY <input type="checkbox"/> OTHER MEDICALLY IMPORTANT CONDITION
M-M	DOMINICAN	Day	Month	Year	69	Male	Day	Month	Year	
	Cont..	19	Feb	1956			Feb	2025		

7+13 DESCRIBE REACTION(S) (including relevant tests/lab data)
 1) Glute pain/Pain in the buttocks and knees (Pain (10033371), Pain (10033371))
 (/Feb/2025 -) - Not Recovered/Not Resolved/Ongoing
 2) Knee pain/Pain in the buttocks and knees (Knee pain (10023477), Arthralgia (10003239))
 (/Feb/2025 -) - Not Recovered/Not Resolved/Ongoing
 3) constipation (Constipation (10010774), Constipation (10010774))
 Unknown

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S)(include generic name) 1) Eligard® (Leuprolide acetate, Leuprolide acetate) (Suspect) (Injection)(Unknown)(Unknown)		20. DID EVENT ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA 21. DID EVENT REAPPEAR AFTER REINTRODUCTION <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA (NA : Not Applicable)
15. DAILY DOSE(S) 1) (45 milligram(s), 1 in 6 Month) 2) (45 milligram(s), 1 in 6 Month)		
16. ROUTE(S) OF ADMINISTRATION 1) Subcutaneous 2) Subcutaneous		
17. INDICATION(S) FOR USE 1) Prostate cancer [10060862 - Prostate cancer]		
18. THERAPY DATE(S) (from/to) 1) (/Feb/2025 - /Feb/2025)	19. THERAPY DURATION 1) 1 Days	

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 <input type="checkbox"/> YES <input type="checkbox"/> NO	24b. MFR CONTROL NO. DO-Tolmar-TLM-2025-04202		
24c. DATE RECEIVED BY MANUFACTURER 07/Jul/2025	24d. REPORT SOURCE <input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL		
DATE OF THIS REPORT 11/Jul/2025	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> 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 Programme (Reference number: DO-ADIUM-DO-0061-20250624) on 24-Jun-2025 from a consumer (non-healthcare professional) regarding an elderly 69-year-old male patient who experienced non-serious events of "knee pain" (arthralgia), "glute pain" (pain) 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 26-Jun-2025.

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

Concomitant medication was unknown.

On 01-Jun-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 an unknown date in Feb-2025, the patient started experiencing severe glute and knee pain. His medication was suspended. No further information reported.

Corrective treatment was unknown.

Action taken with Eligard in response to events was drug withdrawn. De-challenge and re-challenge were not applicable.

The outcomes of arthralgia and pain were not resolved.

The reporter did not assess the seriousness of arthralgia and pain.

The reporter assessed the causality of arthralgia, pain in relationship to Eligard and Eligard unspecified device as related.

No further query was raised.

Note: Since stop date of treatment was given as Feb-2025, also it is captured as event onset date and action taken was reported as Drug withdrawn. Hence, as per medical judgement "suspension of medication" (therapy cessation) was not captured as an event in the case.

On 07-Jul-2025, the follow up was received by Adium via Patient Support Programme (Reference number: DO-ADIUM-DO-0061-20250624 (01)) a consumer (non-healthcare professional) and sent to Tolmar on 08-Jul-2025. New information included: added a non-serious event of "constipation" (constipation) and updated verbatim of "pain" from "Glute pain" to "Glute pain/Pain in the buttocks and knees" and "knee pain" from "Knee pain" to "Knee pain/Pain in the buttocks and knees".

On an unknown date in Feb-2025, the patient pain worsened after 2 days not going to bathroom and suffered constipation which occur after the suspension of treatment. No further information reported.

Corrective treatment was not reported.

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

The outcome of constipation was unknown.

The reporter did not assess the seriousness of constipation.

The reporter did not provide the causality of constipation in relationship to Eligard and Eligard unspecified device.

No further 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

Pain>Eligard® >listed as per CCDS Eligard®> 7-Nov-2024

Pain> Eligard® >listed as per Canadian Monograph Eligard®> 2-Apr-2025

Pain> Eligard®>unlisted as per USPI Eligard®>Feb-2025

Continuation Sheet for CIOMS report

Pain> Eligard® Unspecified Device>unlisted as per USPI Eligard®>Feb-2025

Constipation>Eligard>Unlisted as per CCDS>07-Nov-2024

Constipation>Eligard>Unlisted as per USPI>Feb-2025

Constipation>Eligard unspecified device>Unlisted as per USPI>Feb-2025

Constipation>Eligard>Unlisted as per Canadian monograph>02-Apr-2025

Company Remarks (Sender's Comments) :

Evaluator comment (Tolmar): This is regarding an elderly 69-year-old male patient who experienced non-serious events of "knee pain" (arthralgia), "glute pain" (pain) during Eligard (leuprolide acetate) 45 mg therapy for prostate cancer. Tolmar assessed the reported events as non-serious since they did not meet the ICH seriousness criteria. The causality of event arthralgia and pain was assessed as related to suspect drug component of Eligard(not related to device) considering the known safety profile of the drug. However, elderly age and underlying prostate cancer could be confounding factors for the events.

FU added event of patient had constipation (constipation) during Eligard (leuprolide acetate) 45 mg therapy 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 reported event constipation was considered as related as the contributory role of suspect drug Eligard cannot be ruled out considering known pharmacological profile of the drug. Event constipation was assessed as not related to the device 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
	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 : /Feb/2025 To :/Feb/2025
	2) From : 01/Jun/2024 To :
Therapy Duration	: 1) 1 Days
Action(s) Taken With Drug	: Drug withdrawn

Causality

1) Glute pain/Pain in the buttocks and knees (Pain - 10033371, Pain - 10033371)	
Causality as per reporter	: Related
Causality as per Mfr	: Related
DeChallenge	: Not applicable
ReChallenge	: Not Applicable
2) Knee pain/Pain in the buttocks and knees (Knee pain - 10023477, Arthralgia - 10003239)	
Causality as per reporter	: Related
Causality as per Mfr	: Related
DeChallenge	: Not applicable
ReChallenge	: Not Applicable
3) constipation (Constipation - 10010774, Constipation - 10010774)	
Causality as per reporter	: Not Reported
Causality as per Mfr	: Related

Labeling :

1) Glute pain/Pain in the buttocks and knees	
CORE	Labeled
2) Knee pain/Pain in the buttocks and knees	
CORE	Labeled
3) constipation	
CORE	Labeled

2) Drug	: Eligard® Unspecified Device (Leuprolide acetate)
Active Substance	: 1) Leuprolide acetate

Continuation Sheet for CIOMS report

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) Glute pain/Pain in the buttocks and knees (Pain - 10033371, Pain - 10033371)

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

2) Knee pain/Pain in the buttocks and knees (Knee pain - 10023477, Arthralgia - 10003239)

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

3) constipation (Constipation - 10010774, Constipation - 10010774)

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

Labeling :

- 1) Glute pain/Pain in the buttocks and knees
CORE
- 2) Knee pain/Pain in the buttocks and knees
CORE
- 3) constipation
CORE

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

Dosage Text :

Drug 1 :Eligard®

- 1) ELIGARD 45 MG x 1 LIO x 1 JER
- 2) ELIGARD 45 MG x 1 LIO x 1 JER