SUSPECT ADVERSE REACTION REPORT

SV-Tolmar-TLM-2025-05451

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year	Years		Day	Month	Year	
PRIVACY	EL Cont..	01	Jan	1936	89	Male	04	Aug	2025	

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

1) Bloody stools (Stool bloody (10042144), Haematochezia (10018836))
(04/Aug/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)(15274CUY; UNK; UNK) 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) (/Aug/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) (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	SV-Tolmar-TLM-2025-05451
24c. DATE RECEIVED BY MANUFACTURER: 04/Aug/2025	24d. REPORT SOURCE: ☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT: 08/Aug/2025	25a. REPORT TYPE: ☑ INITIAL ☐ FOLLOWUP

= Continuation attached sheet(s)..

Continuation Sheet for CIOMS report

1a. COUNTRY

EL SALVADOR

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

Event Description :

This study report from El Salvador was received by Adium via 'ASOFARMA A TU LADO' Patient Support Program (reference number: SV-ADIUM-SV-0020-20250804 (0)) on 04-Aug-2025 from a consumer (son) (non-health care professional) regarding an elderly 89-year-old male patient who experienced a serious (medically significant) event of "Bloody stools" (Haematochezia) during Eligard (leuprolide acetate) 22.5 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 05-Aug-2025.

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

Concomitant medications were unknown.

On an unknown date in Aug-2024, the patient began receiving Eligard 22.5 mg, every 3 months via subcutaneous route for prostate cancer (Lot numbers and Expiration dates were not provided).

On 04-Aug-2025, the patient experienced bloody stool. It was reported the patient has moderate bleeding and was currently stable. It was advised to consult the treating physician for treatment. No further details were provided.

Corrective treatment was not reported.

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

The outcome of haematochezia was not recovered.

The reporter did not assess the seriousness of haematochezia.

The reporter assessed the causality of hematochezia in relationship to Eligard and Eligard Unspecified device as related.

No further information is expected as consent to be contacted was not provided.

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

Company Remarks (Sender's Comments) :

Evaluator comment (Tolmar): This is regarding an elderly 89-year-old male patient who experienced event of Haematochezia (Bloody stools) during Eligard (leuprolide acetate) 22.5 mg therapy for prostate cancer. Tolmar assessed the reported event as serious as it is included in IME list. The causality of event haematochezia was assessed as not related to suspect Eligard(drug and device) considering the nature of event, inconsistency with safety profile of the drug, etiology of event, elderly age and underlying prostate cancer could be confounders 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) 15274CUY; UNK; UNK
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 : /Aug/2024 To :Unknown
Action(s) Taken With Drug	: Unknown

Causality

1) Bloody stools (Stool bloody - 10042144, Haematochezia - 10018836)
Causality as per reporter : Related

Continuation Sheet for CIOMS report

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

Labeling :

1) Bloody stools
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) 15274CUY; UNK; UNK
Route of Admin : 1) Unknown
Indications : 1) PROSTATE CANCER [10060862 - Prostate cancer]
Action(s) Taken With Drug : Not applicable

Causality

1) Bloody stools (Stool bloody - 10042144, Haematochezia - 10018836)
Causality as per reporter : Related
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) Bloody stools
CORE