CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

HN-Tolmar-TLM-2025-02039

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	
MRC	HONDURAS	09	Sep	1946	78	Male		Apr	2025	

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

1) Cough without expectoration, without phlegm (Dry cough (10013773), Cough (10011224)) (/Apr/2025 -) - Recovering/Resolving

- ☐ 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) 0.267 milligram(s) (45 milligram(s), 1 in 24 Week)

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) (//2021 - 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	HN-Tolmar-TLM-2025-02039
24c. DATE RECEIVED BY MANUFACTURER: 16/May/2025	24d. REPORT SOURCE: ☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT: 24/May/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 Honduras was received by Adium (reference number: HN-ADIUM-HN-0209-20250516) via Patient Support Program on 16-May-2025 from a consumer (non-health care professional) regarding a 78-year-old male patient who had experienced “Cough without expectoration, without phlegm” (Cough) 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 19-May-2025.

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

Concomitant medication was unknown.

On an unknown date in 2021, the patient began receiving Eligard 45mg, every 24 weeks via subcutaneous route for prostate cancer (Lot numbers and Expiration dates were not provided).

On an unknown date in Apr-2025, the patient started experiencing mild cough without expectoration, without phlegm and without fever for more than 1 month. He started taking syrup, but it doesn't go away, and he had difficulty to do physical exercises.

Corrective treatment included oral Viscof D syrup.

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

The outcome of cough was recovering.

The reporter did not assess the seriousness of cough.

The reporter did not assess the causality of cough in relationship to Eligard and Eligard Unspecified device.

No further information is not expected as the reporter did not provided consent to be contacted for follow-up.

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

Company Remarks (Sender's Comments) :

Evaluator comment (Tolmar): This case is regarding an elderly 78-year-old male patient who had experienced Cough (Cough without expectoration, without phlegm) during Eligard (leuprolide acetate) 45 mg therapy for prostate cancer. Tolmar assessed the reported event as non-serious since it did not meet the ICH seriousness criteria. The causality of event cough was assessed as not related to suspect Eligard(drug and device) considering the nature of event and inconsistency with the safety profile of the drug.

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	:	1) 0.267 milligram(s) (45 milligram(s), 1 in 24 Week)
Route of Admin	:	1) Subcutaneous
Indications	:	1) Prostate cancer [10060862 - Prostate cancer]
Therapy Dates	:	1) From : //2021 To :Continuing
Action(s) Taken With Drug	:	Dose not changed

Causality

1) Cough without expectoration, without phlegm (Dry cough - 10013773, Cough - 10011224)

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) Cough without expectoration, without phlegm
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
Indications : 1) Prostate cancer [10060862 - Prostate cancer]
Action(s) Taken With Drug : Not applicable

Causality

1) Cough without expectoration, without phlegm (Dry cough - 10013773, Cough - 10011224)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) Cough without expectoration, without phlegm
CORE