SUSPECT ADVERSE REACTION REPORT

HN-Tolmar-TLM-2025-01772

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
JAE	HONDURAS	12	Apr	1953	72	Male			

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

1) Suspension of treatment by medical decision due to disease progression (Disease progression (10061818), Disease progression (10061818))
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) (45 Milligram, Injection)(Unknown)

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

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) PROGRESSION OF THE DISEASE SUSPENSION BY MEDICAL DECISION ((10061818, Disease progression) (//2024 -) (Continuing: Yes)

Cont..

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-2025-01772
24c. DATE RECEIVED BY MANUFACTURER: 14/May/2025	24d. REPORT SOURCE: ☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT: 23/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 via patient support program (Asofarma A Tu Lado) (reference number: HN-ADIUM-HN-0205-20250514) on 14-May-2025, from a consumer (patient family member) regarding an elderly-72-year-old male patient who experienced a non-serious event of 'suspension of treatment by medical decision due to disease progression' (disease progression) 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 15-May-2025.

The patient's medical history was unknown, and current condition was prostate cancer and disease progression.

Concomitant medications were unknown.

On an unknown date, the patient began receiving Eligard 45 mg, every 6 months via subcutaneous route for prostate cancer (Lot numbers and expiration dates were unknown).

On an unknown date, the patient was informed for the suspension of treatment by medical decision due to disease progression. Intensity of event was Moderate.

It was reported that the sign or symptom experienced was not related to the product administered. No further details were provided.

Corrective treatment was unknown.

Action taken with Eligard in response to event was drug withdrawn.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

The outcome of disease progression was not resolved.

The reporter did not assess the seriousness of disease progression.

The reporter assessed the causality of disease progression in relation to Eligard and Eligard Unspecified Device as not related.

No follow up queries were raised.

Listedness:
Disease progression>Eligard>listed as per CCDS>07-Nov-2024
Disease progression>Eligard>listed as per USPI>Feb-2025
Disease progression>Eligard unspecified device>listed as per USPI>Feb-2025
Disease progression>Eligard>listed as per Canadian monograph>O2-Apr-2025

Company Remarks (Sender's Comments) :

Evaluator Comment (Tolmar): This 72-year-old male patient had Disease progression (Suspension of treatment by medical decision due to disease progression) during Eligard (leuprolide acetate) 45 mg therapy for prostate cancer. Tolmar assessed the event Disease progression as non-serious based on available limited information and no mention of immediate jeopardy to patient. Underlying malignancy prostate cancer can be considered confounding factor for the reported event. Disease progression was assessed as not related to Eligard (drug and device component) as causal role of the drug could not be established with limited available information.

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

Product-Reaction Level

1) Drug	:	Eligard® (Leuprolide acetate)
Active Substance	:	1) Leuprolide acetate
Drug Characterization	:	Suspect
Form Strength	:	1) 45 Milligram
Form of Admin	:	1) Injection
Lot Number	:	1) Unknown
Daily Dose	:	(45 milligram(s), 1 in 6 Month)
Route of Admin	:	1) Subcutaneous
Indications	:	1) Prostate cancer [10060862 - Prostate cancer]
Action(s) Taken With Drug	:	Drug withdrawn

Causality

1) Suspension of treatment by medical decision due to disease progression (Disease progression - 10061818, Disease progression - 10061818)
Causality as per reporter : Not Related

Continuation Sheet for CIOMS report

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

Labeling :

1) Suspension of treatment by medical decision due to disease progression
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
Indications : 1) Prostate cancer [10060862 - Prostate cancer]
Action(s) Taken With Drug : Not applicable

Causality

1) Suspension of treatment by medical decision due to disease progression (Disease progression - 10061818, Disease progression - 10061818)
Causality as per reporter : Not Related
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) Suspension of treatment by medical decision due to disease progression
CORE

23. OTHER RELEVANT HISTORY (Continuation...)

2) PROSTATE CANCER (10060862 , Prostate cancer) (Continuing : YES)