SUSPECT ADVERSE REACTION REPORT

PA-Tolmar-TLM-2025-01013

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
		Day	Month	Year			Day	Month	Year	
W-P	PANAMA	08	Apr	1944	81	Male	15	Apr	2025	

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

1) Completely decompensated (Chronic disease (10076311), Chronic disease (10076311))
(15/Apr/2025 -) - Not Recovered/Not Resolved/Ongoing
2) Completely decompensated (Condition worsened (10076326), Condition aggravated (10010264))
(15/Apr/2025 -) - Not Recovered/Not Resolved/Ongoing
3) High blood sugar (Blood glucose increased (10005557), Blood glucose increased (10005557))
(15/Apr/2025 -) - Not Recovered/Not Resolved/Ongoing

Cont..

- ☐ 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) (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) (01/Apr/2024 - ongoing)	

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

1)XTANDI(ENZALUTAMIDE)(Capsule)(01/Apr/2024 -)

Cont..

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-2025-01013
24c. DATE RECEIVED BY MANUFACTURER: 21/Apr/2025	24d. REPORT SOURCE: ☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT: 03/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 Invalid case report from PANAMA was received by Adium PSP - Prevenfuturo (reference number: PA-ADIUM-PA-0023-20250317) on 17-MAR-2025 from Consumer/Other Non-Health Prof and sent to Tolmar on 18-MAR-2025.

This report was assessed as invalid as no adverse event was reported. The reported term was not considered an adverse event because the reason for the surgery was not provided.

Abbreviated Narrative
This report was assessed as invalid as no adverse event was reported. The reported term was not considered an adverse event because the reason for the surgery was not provided. This report was assessed as invalid as no adverse event was reported. The reported term was not considered an adverse event because the reason for the surgery was not provided.

On 21-Apr-2025, follow up information was received by Adium (reference number: PA-ADIUM-PA-0023-20250317) from a consumer (family member) and sent to Tolmar on 22-Apr-2025. New information included: Case upgraded from invalid to valid. New serious (hospitalization and medically significant) events added as “High blood sugar” (Blood glucose increased) and ‘Completely decompensated' (Chronic disease and condition aggravated). Lab investigation added as “blood glucose". Action taken updated.

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

Concomitant medications were Xtandi (enzalutamide).

On 13-Mar-2025, the patient had a toe to be amputated.

On Tuesday, 18-Mar-2024, the discharge from the hospital was anticipated. No further details were provided.

On 01-Apr-2024, the patient began receiving Eligard 45 mg every 6 months via subcutaneous route for prostate cancer (Lot numbers and expiration dates were unknown).

On 15-Apr-2025, the patient had been hospitalized due to elevated blood sugar level and was found to be completely decompensated. No further details were provided.

Corrective treatment was unknown.

Relevant test results included:
On 15-Apr-2025: blood glucose: high blood sugar (Ref range: not provided).

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

The outcome of blood glucose increased, chronic disease and condition aggravated was not recovered.

The reporter assessed the seriousness of blood glucose increased, chronic disease and condition aggravated as serious (hospitalization).

The reporter did not provide the causality of blood glucose increased, chronic disease and condition aggravated in relationship to Eligard and Eligard Unspecified Device.

Listedness:

Blood glucose increased>Eligard>Unlisted as per CCDS>07-Nov-2024
Blood glucose increased>Eligard>Unlisted as per USPI>Feb-2025
Blood glucose increased>Eligard unspecified device>Unlisted as per USPI>Feb-2025
Blood glucose increased>Eligard>Unlisted as per Canadian monograph>02-Apr-2025

Chronic disease>Eligard>Unlisted as per CCDS>07-Nov-2024
Chronic disease>Eligard>Unlisted as per USPI>Feb-2025
Chronic disease>Eligard unspecified device>Unlisted as per USPI>Feb-2025
Chronic disease>Eligard>Unlisted as per Canadian monograph>02-Apr-2025

Condition aggravated>Eligard>Unlisted as per CCDS>07-Nov-2024
Condition aggravated>Eligard>Unlisted as per USPI>Feb-2025
Condition aggravated>Eligard unspecified device>Unlisted as per USPI>Feb-2025
Condition aggravated>Eligard>Unlisted as per Canadian monograph>02-Apr-2025

Company Remarks (Sender's Comments) :

Continuation Sheet for CIOMS report

Evaluator comment (Tolmar): This is regarding an elderly 81-year-old male patient who experienced blood glucose increased (high blood sugar), chronic disease and condition aggravated (completely decompensated) during Eligard (leuprolide acetate) 45 mg therapy for prostate cancer. Tolmar assessed the reported event as serious (hospitalisation and medically significant) since the patient was hospitalised in response to events. The reported event blood glucose increased is assessed as related Eligard (drug) considering known pharmacological profile of the drug. The events chronic disease and condition aggravated could not be assessed conclusively for events chronic disease and condition aggravated for drug Eligard due to lack of sufficient information regarding clinical details, exact condition that was decompensated, relevant medical history if any, concomitant medication details, lab reports if any. All the reported events were assessed as not related to device component of Eligard.

Additional Information (Continuation...)

Lab Result :

Test Name	Test Date	Test Result	Normal Value
BLOOD GLUCOSE	15/Apr/2025		

Test Result (Code) / Result Unstructured Data (free text) :

1) Test Name: BLOOD GLUCOSE

Result Unstructured Data (free text) : High blood sugar

Test Date: 15/Apr/2025

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 : (45 milligram(s), 1 in 6 Month)
Route of Admin : 1) Subcutaneous
Indications : 1) Prostate cancer [10060862 - Prostate cancer]
Therapy Dates : 1) From : 01/Apr/2024 To :Continuing
Action(s) Taken With Drug : Dose not changed

Causality

1) Completely decompensated (Chronic disease - 10076311, Chronic disease - 10076311)
Causality as per reporter : Not Reported
Causality as per Mfr : Not assessable
DeChallenge : Not applicable
ReChallenge : Not Applicable

2) Completely decompensated (Condition worsened - 10076326, Condition aggravated - 10010264)
Causality as per reporter : Not Reported
Causality as per Mfr : Not assessable
DeChallenge : Not applicable
ReChallenge : Not Applicable

3) High blood sugar (Blood glucose increased - 10005557, Blood glucose increased - 10005557)
Causality as per reporter : Not Reported
Causality as per Mfr : Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) Completely decompensated
CORE UnLabeled
2) Completely decompensated
CORE UnLabeled
3) High blood sugar
CORE UnLabeled

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

Continuation Sheet for CIOMS report

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) Completely decompensated (Chronic disease - 10076311, Chronic disease - 10076311)

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

2) Completely decompensated (Condition worsened - 10076326, Condition aggravated - 10010264)

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

3) High blood sugar (Blood glucose increased - 10005557, Blood glucose increased - 10005557)

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

Labeling :

1) Completely decompensated
   CORE
2) Completely decompensated
   CORE
3) High blood sugar
   CORE

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

Dosage Text :

Drug 1 :Eligard®

1) ELIGARD 45 MG x 1 LIO x 1 JER

22.CONCOMITANT DRUG(S) (Continuation...)

1). Drug	:	XTANDI
Active Substance	:	1) ENZALUTAMIDE
Form Strength	:	
Form of Admin	:	1) Capsule
Daily Dose	:	1) 160.0 milligram(s) (40 milligram(s), 4 in 1 Day)
Route of Admin	:	1) Oral
Indications	:	1) Prostate cancer [10060862 - Prostate cancer]
Therapy Dates	:	1) From : 01/Apr/2024 To :
Dosage Text	:	1) 40 milligram, qid XTANDI 40 MG x 120 CAP x 30 FND