SUSPECT ADVERSE REACTION REPORT

DO-Tolmar-TLM-2025-01620

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	
JENB	DOMINICAN Cont..	05	Jun	1943	81	Male				

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

1) High glucose/Elevated glucose (Glucose increased (10018421), Blood glucose increased (10005557))
Unknown

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)(Unknown)(Unknown)

Cont..

20. DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☑ NA

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
1) (45 milligram(s), 1 in 6 Month)	1) Subcutaneous
2) (45 milligram(s), 1 in 6 Month)	2) 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) (23/Apr/2024 - Ongoing)	

III. CONCOMITANT DRUG(S) AND HISTORY

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

1)B Complex(CALCIUM PANTOTHENATE)

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	DO-Tolmar-TLM-2025-01620
24c. DATE RECEIVED BY MANUFACTURER	24d. REPORT SOURCE
07/May/2025	☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT	25a. REPORT TYPE
20/May/2025	☑ INITIAL ☐ 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 the 'ASOFARMA A TU LADO' Patient Support Program (reference number: DO-ADIUM-DO-0032-20250507) on 07-May-2025 from a consumer (patient's wife) (non-healthcare professional) regarding an elderly 81-year-old male patient who experienced a non-serious event of "high glucose/elevated glucose" (blood glucose increased) during Eligard (Leuprolide acetate) 45 milligram therapy for prostate cancer. The needle component of the constituent device was not identified in the report. The report was sent to Tolmar on 12-May-2025.

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

Concomitant medications were iron, folic acid, B-complex and calcium.

On 23-Apr-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, Patient's wife mentioned that the patient had maintained his glucose levels in the mid-70s (referring to 70 and a fraction of the levels). She mentioned that her doctor told her that this was not something they should adjust, as it might be due to the patient's age or the use of Eligard, but the patient's wife mentioned that the doctor didn't assure her that the elevated glucose was due to using Eligard. He only advised her to check if that was the reason for the elevation but also advised that the patient be observed to validate how it was holding up. She mentions that she has taken measures with the patient, such as not giving him sugar or juice. She stated that she didn't know what the patient's glucose level was when he received the first dose of Eligard.

The patient's wife commented that the patient had received three doses of Eligard. She didn't have the lot number or expiration date for Eligard.

On 01-May-2025, she only mentioned that the patient's received his most recent dose.

On 01-Nov-2025 (proposed future date) the next dose was scheduled. The patient has an appointment with his cardiologist every six months.

Corrective treatment was not reported.

Relevant test results included:
On an unknown date: Glucose test: Result: Not provided
On an unknown date in end of 2024: Glucose Test: 100 mg/dL.
On an unknown date in Jan-2025: Glucose Test: 104 mg/dL

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

The outcome of was blood glucose increased was unknown.

The reporter did not assess the seriousness or causality of the event in relationship to Eligard and Eligard unspecified device.

No further queries were raised.

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

Company Remarks (Sender's Comments) :

Evaluator comment (Tolmar): This is regarding 81-year-old elderly male patient who had blood glucose increased ("high glucose/elevated glucose"), 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 blood glucose increased was assessed as related to Eligard (drug) considering the known safety profile of the drug. Patients age is a confounder for causality assessment. The reported event blood glucose increased was assessed as not related to Eligard (device).

Additional Information (Continuation...)

Lab Result :

Continuation Sheet for CIOMS report

Test Name	Test Date	Test Result	Normal Value
GLUCOSE TEST	//2024	100 milligram per decilitre	
GLUCOSE TEST	/Jan/2025	104 milligram per decilitre	
GLUCOSE TEST			

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

3) Test Name: GLUCOSE TEST

Result Unstructured Data (free text) : Elevated

Test Date:

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
3) Injection
Lot Number : 1) Unknown
2) Unknown
3) Unknown
Daily Dose : (45 milligram(s), 1 in 6 Month)
(45 milligram(s), 1 in 6 Month)
(45 milligram(s), 1 in 6 Month)
Route of Admin : 1) Subcutaneous
2) Subcutaneous
3) Subcutaneous
Indications : 1) Prostate cancer [10060862 - Prostate cancer]
Therapy Dates : 1) From : 23/Apr/2024 To :Continuing
2) From : 01/May/2025 To :Continuing
Action(s) Taken With Drug : Dose not changed

Causality

1) High glucose/Elevated glucose (Glucose increased - 10018421, Blood glucose increased - 10005557)
Causality as per reporter : Related
Causality as per Mfr : Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) High glucose/Elevated glucose
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
Route of Admin : 1) Subcutaneous
Indications : 1) prostate cancer [10060862 - Prostate cancer]
Action(s) Taken With Drug : Not applicable

Causality

1) High glucose/Elevated glucose (Glucose increased - 10018421, Blood glucose increased - 10005557)
Causality as per reporter : Related
Causality as per Mfr : Not Related
DeChallenge : Not applicable

Continuation Sheet for CIOMS report

ReChallenge : Not Applicable

Labeling :

1) High glucose/Elevated glucose
CORE

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

1). Drug	:	B Complex
Active Substance	:	1) CALCIUM PANTOTHENATE 2) NICOTINAMIDE 3) PROCAINE HYDROCHLORIDE 4) PYRIDOXINE HYDROCHLORIDE 5) RIBOFLAVIN 6) THIAMINE HYDROCHLORIDE
Form Strength	:	
Indications	:	1) drug use for unknown indication [10057097 - Drug use for unknown indication]

2). Drug	:	IRON FERROUS SULFATE
Active Substance	:	1) FERROUS SULFATE
Form Strength	:	
Indications	:	1) Drug use for unknown indication [10057097 - Drug use for unknown indication]

3). Drug	:	CALCIUM
Active Substance	:	1) CALCIUM
Form Strength	:	
Indications	:	1) Drug use for unknown indication [10057097 - Drug use for unknown indication]

4). Drug	:	FOLIC ACID
Active Substance	:	1) FOLIC ACID
Form Strength	:	
Indications	:	1) Drug use for unknown indication [10057097 - Drug use for unknown indication]