SUSPECT ADVERSE REACTION REPORT

GT-TOLMAR, INC.-24GT046568

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
ELDA	GUATEMALA	03	Sep	1963	60	Male	28	Nov	2023

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

1) Feeling of warmth on the soles of the feet/the soles of his feet getting hot / has also been very hot (Hot feeling in feet (10020405), Feeling hot (10016334))
(28/Nov/2023 -) - Unknown
2) mood changes (Mood altered (10027940), Mood altered (10027940))
(28/Nov/2023 -) - Unknown
3) Very warm sensation/ a lot of hot flashes (sensation of a lot of heat) (Hot flashes (10020407), Hot flush (10060800))
(28/Nov/2023 -) - Unknown
4) STARTED ELIGARD AS 18 OCT 2023 AND RECEIVED LAST DOSE ON 17 JAN 2024 (Drug dose administration interval too short (10064319), Inappropriate schedule of product administration (10081572))
(17/Jan/2024 - 17/Jan/2024) - Recovered/Resolved

Cont..

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) (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) (12/Jun/2023 - 22-Jan-2025)	

III. CONCOMITANT DRUG(S) AND HISTORY

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

1)RADIOTHERAPY(RADIOTHERAPY)(/Jun/2023 - /Aug/2023)

Cont..

23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

1) FALL (10016173, Fall) (//2014 -) (Continuing: No)

Cont..

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	GT-TOLMAR, INC.-24GT046568
24c. DATE RECEIVED BY MANUFACTURER	24d. REPORT SOURCE
30/Jul/2025	☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT	25a. REPORT TYPE
05/Aug/2025	☐ INITIAL ☑ FOLLOWUP

= Continuation attached sheet(s)..

Continuation Sheet for CIOMS report

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

5) Cessation of therapy (Therapy cessation (10065154), Therapy cessation (10065154)(22/Jan/2025 -) - Unknown)

Event Description :

This Study report from GUATEMALA was received by Adium via Patient Support Program "ASOFARMA A TU LADO" (reference number: GT-ADIUM-GT-0063-20240131) on 31-JAN-2024 from a Consumer/Other Non-Health Prof regarding a 60 Years old Male patient reporting non-serious events of “the soles of his feet getting hot / has also been very hot (Hot feeling in feet)”, “mood changes (Mood altered)”, “a lot of hot flashes (sensation of a lot of heat) (Hot flashes)” and "started Eligard as 18 Oct 2023 and received last dose on 17 Jan 2024 (Drug dose administration interval too short)", 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 01-FEB-2024.

The patient's medical history included Fall. Current conditions included Prostate cancer and Joint injury. Procedures included Hip arthroplasty and Radical prostatectomy.

Concomitant medications included RADIOTHERAPY.

Patient underwent a biopsy in November 2022, in the biopsy via the rectum they extracted some particles from his prostate where it helped them to determine at the end of December 2022, he was detected with high-risk prostate cancer where he had to undergo emergency surgery, on December 22, 2022. In December 2022 they also diagnosed the problem in his hip, he started the radiotherapies in June 2023 and in August 2023 he finished 35 sessions of radiotherapies. The treating doctor informed him that he was expected on January 2, 2023, and on January 9, 2023, a radical prostatectomy was performed which was an open surgery for the removal of the prostate. On 18-OCT-2023, the patient began receiving Eligard 45 milligram, q 6 month, via Subcutaneous use, for Prostate cancer (Lot details unknown). Then he returned to the hospital where on November 20, 2023, a complete hematology was performed and in the same month on November 28, 2023, they intervened performing a hip replacement surgery thus being a prosthesis in the hospital, which was a success. It was commented that the reason for the surgery was because he had suffered a fall 10 years ago. On 28-NOV-2023, 1 month 11 days after the initial dose of Eligard, he presented side effects of the soles of his feet getting hot (sensation of heat in the feet), a lot of hot flashes (sensation of a lot of heat) and mood changes (mood alteration). Additionally, it was mentioned that it was not something to be alarmed about since he had also been very hot. Every time he went for an application appointment, free and total PSA tests were performed. Corrective treatment was not reported. On 17-JAN-2024, the patient received Eligard 45 milligram, q 6 month, via Subcutaneous use, for Prostate cancer (Lot details unknown) and as reported patient started Eligard as 18 Oct 2023 and received last dose on 17 Jan 2024. Action taken with Eligard in response to the events was Dose Not Changed. De-challenge and re-challenge were not applicable. The outcome of Hot feeling in feet was Unknown. The outcome of Mood altered was Unknown. The outcome of Hot flashes was Unknown. The outcome of Drug dose administration interval too short was Recovered/Resolved on 17-Jan-2024.

Relevant test results included:
DEC-2022: Biopsy: he was detected with high-risk prostate cancer (Ref range: Not provided)
20-NOV-2023: Blood test: complete hematology performed (unknown results) (Ref range: Not provided)
Unknown date: Prostatic specific antigen: Unknown results (Ref range: Not provided)

The reporter did not assess the seriousness or causality of the events in relationship to Eligard.

On 16-Jun-2025 and 17-Jun-2025, follow-up information was received by Adium via Patient Support Program “Asofarma a tu Lado” (reference number: GT-ADIUM-GT-0063-2024013) from a consumer (non-healthcare professional) and sent to Tolmar on 17-Jun-2025. New information included: added a new non-serious event of "Cessation of therapy" (Therapy cessation) and start date; 12-Jun-2023 and end of treatment added 22-Jan-2025 were added, and Weight of the patient (kg): 86.00 - Height of the patient (cm): 172 is added.

On 12-Jun-2023, patient started Eligard 45 mg every six months via subcutaneous route for prostate cancer (Lot number and expiry dates were not provided).

On 22-Jan-2025, patient received latest dose of Eligard 45 mg every six months via subcutaneous route for prostate cancer (Lot number and expiry dates were not provided).

Corrective treatment was not reported.

Action taken with Eligard in response to the events was Drug withdrawn. De-challenge and re-challenge were not applicable.

The outcome of therapy cessation was Unknown.

The reporter did not assess the seriousness of therapy cessation.

The reporter did not provide the causality of therapy cessation in relationship to Eligard and Eligard unspecified device.

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

Feeling hot>Eligard>Unlisted as per CCDS>07-Nov-2024
Feeling hot>Eligard>Unlisted as per USPI>Feb-2025
Feeling hot>Eligard unspecified device>Unlisted as per USPI>Feb-2025

Continuation Sheet for CIOMS report

Feeling hot>Eligard>Unlisted as per Canadian monograph>02-Apr-2025

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

Hot Flush>Eligard>Listed as per CCDS>07-Nov-2024
Hot Flush>Eligard>Listed as per USPI>Feb-2025
Hot Flush>Eligard unspecified device>Listed as per USPI>Feb-2025
Hot Flush>Eligard>Listed as per Canadian monograph>02-Apr-2025

Inappropriate schedule of product administration>Eligard>Unlisted as per CCDS>07-Nov-2024
Inappropriate schedule of product administration>Eligard>Unlisted as per USPI>Feb-2025
Inappropriate schedule of product administration>Eligard unspecified device>Unlisted as per USPI>Feb-2025
Inappropriate schedule of product administration>Eligard>Unlisted as per Canadian monograph>02-Apr-2025

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

Follow up information was received on 07-Jul-2025, via an electronic form through the Jazz Safety tool of the Patient Support Program “ASOFARMA A TU LADO”:
The email address of the notifier has been corrected. This follow up information considered to be non-significant.

On 30-Jul-2025, follow up information was received by Adium via Patient Support Program "ASOFARMA A TU LADO" (reference number: GT-ADIUM-GT-0063-20240131 (3)), from a consumer and sent to Tolmar on 31-Jul-2025. New information included: the start date for prostate cancer was added as Dec-2023.

No new significant information received in follow up. Listedness is retained as per previous version.

Company Remarks (Sender's Comments) :

Evaluator comment (Tolmar): This is regarding a 60 Years old male patient reporting non-serious events of feeling hot (the soles of his feet getting hot / has also been very hot), mood altered (mood changes), hot flashes (a lot of hot flashes (sensation of a lot of heat), inappropriate schedule of product administration (started Eligard as 18 Oct 2023 and received last dose on 17 Jan 2024) and therapy cessation (cessation of therapy), during Eligard (Leuprolide acetate) 45 milligram therapy for prostate cancer. Tolmar assessed the reported events as non-serious since they did not meet the ICH seriousness criteria and are not IME events. The reported events feeling hot, mood altered and hot flushes are assessed as related with company drug Eligard based on plausible temporal relationship and known safety profile of the drug (not related with device). Patient's medical history of radiotherapies and radical prostatectomy are significant risk factors in the case. The causality for the reported events inappropriate schedule of product administration and therapy cessation is assessed as not related with Eligard (drug and device) components as the events happened due to human action rather due to the product.

No new significant information received in follow up. Causality is retained as per the previous version.

Additional Information (Continuation...)

Lab Result :

Test Name	Test Date	Test Result	Normal Value
BIOPSY	/Dec/2022		
COMPLETE HEMATOLOGY	20/Nov/2023		
PSA	Unknown		

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

1) Test Name: BIOPSY

Result Unstructured Data (free text) : he was detected with high risk prostate cancer

Test Date: /Dec/2022

2) Test Name: COMPLETE HEMATOLOGY

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Result Unstructured Data (free text) : complete hematology performed (unknown results)
Test Date: 20/Nov/2023

3) Test Name: PSA

Result Unstructured Data (free text) : Unknown results
Test Date: Unknown

Lab Comments :

1) Test Name : BIOPSY

Lab Comments : he was detected with high risk prostate cancer

2) Test Name : COMPLETE HEMATOLOGY

Lab Comments : complete hematology performed (unknown results)

3) Test Name : PSA

Lab Comments : Unknown results

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 : 12/Jun/2023 To : 2) From : 18/Oct/2023 To : 3) From : 17/Jan/2024 To :
Action(s) Taken With Drug	:	Drug withdrawn

Causality

1) Feeling of warmth on the soles of the feet/the soles of his feet getting hot / has also been very hot (Hot feeling in feet - 10020405, Feeling hot - 10016334)

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

2) mood changes (Mood altered - 10027940, Mood altered - 10027940)

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

3) Very warm sensation/ a lot of hot flashes (sensation of a lot of heat) (Hot flashes - 10020407, Hot flush - 10060800)

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

4) STARTED ELIGARD AS 18 OCT 2023 AND RECEIVED LAST DOSE ON 17 JAN 2024 (Drug dose administration interval too short - 10064319, Inappropriate schedule of product administration - 10081572)

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

5) Cessation of therapy (Therapy cessation - 10065154, Therapy cessation - 10065154)

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

Labeling :

1) Feeling of warmth on the soles of the feet/the soles of his feet getting hot / has also been very hot
CORE UnLabeled
2) mood changes
CORE UnLabeled
3) Very warm sensation/ a lot of hot flashes (sensation of a lot of heat)
CORE Labeled
4) STARTED ELIGARD AS 18 OCT 2023 AND RECEIVED LAST DOSE ON 17 JAN 2024
CORE UnLabeled
5) Cessation of therapy
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
Route of Admin : 1) Subcutaneous
Indications : 1) prostate cancer [10060862 - Prostate cancer]
Action(s) Taken With Drug : Not applicable

Causality

1) Feeling of warmth on the soles of the feet/the soles of his feet getting hot / has also been very hot (Hot feeling in feet - 10020405, Feeling hot - 10016334)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
2) mood changes (Mood altered - 10027940, Mood altered - 10027940)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
3) Very warm sensation/ a lot of hot flashes (sensation of a lot of heat) (Hot flashes - 10020407, Hot flush - 10060800)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
4) STARTED ELIGARD AS 18 OCT 2023 AND RECEIVED LAST DOSE ON 17 JAN 2024 (Drug dose administration interval too short - 10064319, Inappropriate schedule of product administration - 10081572)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
5) Cessation of therapy (Therapy cessation - 10065154, Therapy cessation - 10065154)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) Feeling of warmth on the soles of the feet/the soles of his feet getting hot / has also been very hot
CORE
2) mood changes
CORE
3) Very warm sensation/ a lot of hot flashes (sensation of a lot of heat)
CORE
4) STARTED ELIGARD AS 18 OCT 2023 AND RECEIVED LAST DOSE ON 17 JAN 2024
CORE
5) Cessation of therapy
CORE

Continuation Sheet for CIOMS report

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

Dosage Text :

Drug 1 :Eligard®

1) 45 milligram, q 6 month

2) 45 milligram, q 6 month

3) 45 milligram, q 6 month

Drug 2 :Eligard® Unspecified Device

1) UNK

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

1). Drug	:	RADIOTHERAPY
Active Substance	:	1) RADIOTHERAPY
Form Strength	:	
Indications	:	1) Product used for unknown indication [10070592 - Product used for unknown indication]
Therapy Dates	:	1) From : /Jun/2023 To : /Aug/2023

23. OTHER RELEVANT HISTORY (Continuation...)

2) HIP PROBLEM (10053220 , Hip injury) (/Dec/2022 -) (Continuing : YES)

3) RADICAL PROSTATECTOMY (10050756 , Radical prostatectomy) (09/Jan/2023 -) (Continuing : NO)

4) HIP REPLACEMENT (10020102 , Hip replacement) (28/Nov/2023 -) (Continuing : NO)

5) PROSTATE CANCER (10060862 , Prostate cancer) (/Dec/2023 -) (Continuing : YES)