SUSPECT ADVERSE REACTION REPORT

GT-TOLMAR, INC.-24GT055020

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
VSM	GUATEMALA	22	Sep	1959	65	Male			

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

1) FELT AS IF HE HAD FIRE IN HIS LEGS AND THEY FELL ASLEEP (Burning sensation of lower limb (10080423), Burning sensation (10006784))
Unknown
2) FELT AS IF HE HAD FIRE IN HIS LEGS AND THEY FELL ASLEEP (Numbness in leg (10029839), Hypoaesthesia (10020937))
Unknown

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)

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) (22/May/2023 - Unknown)	

III. CONCOMITANT DRUG(S) AND HISTORY

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

1)TEOPRIN(BICALUTAMIDE)(50 Milligram)

Cont..

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

1) PROSTATE CANCER (10060862, Prostate cancer) (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	GT-TOLMAR, INC.-24GT055020
24c. DATE RECEIVED BY MANUFACTURER: 20/Apr/2025	24d. REPORT SOURCE: ☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT: 02/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 GUATEMALA was received by Aduim via Asofarma a tu lado Patient Support Program (reference number: GT-ADIUM-GT-0557-20241213) on 13-DEC-2024 from a Consumer/Other Non-Health Prof regarding an Elderly old Male patient who Felt as if he had fire in his legs and they fell asleep (Burning sensation of lower limb, Numbness in leg), 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 16-DEC-2024.

The patient's medical history and current conditions included Prostate cancer, Diabetes mellitus.

Concomitant medications included TEOPRIN, METFORMIN.

On 22-MAY-2023, the patient began receiving Eligard 45 milligram, q 6 month via Subcutaneous use for Prostate cancer (Lot numbers and Expiration dates were not provided). On an unknown date, unknown time after the most recent dose of Eligard, the patient felt as if he had fire in his legs and they fell asleep. On NOV-2023, approximately 6 months after the most recent dose of Eligard, the patient ended his cycle of 36 radiotherapies. On 11-JUL-2024, the patient received Eligard 45 milligram, q 6 month via Subcutaneous use (Lot numbers and Expiration dates were not provided). On 15-NOV-2024, approximately one year and a half after the most recent dose of Eligard, the free and total prostatic antigen was normal (results not provied). At the end of NOV-2024, he went to an appointment with the urologist and he indicated that the Eligard treatment was prescribed for 2 years, but that Eligard would be suspended for 6 months to verify if the free and total prostatic antigen was maintained at the same level or if the antigen tended to rise again during the 6 months. If the free and total prostatic antigen did not increase, Eligard would be suspended until further notice. On JAN-2025, the chest, prostate antigen test and hormone test would be performed. Corrective treatment was not reported. Action taken with Eligard in response to the events was Unknown. De-challenge and re-challenge were Not applicable. The outcome of Burning sensation of lower limb and Numbness in leg was Unknown.

Relevant test results included:
15-NOV-2024: Prostatic specific antigen normal (Ref range: Not provided)

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

On 20-Apr-2025, follow up was received by Aduim (reference number: GT-ADIUM-GT-0557-20241213) on 20-Apr-2025. No new information received.

Note: study type from "spontaneous" to "study" and sex as "male" was already updated by the previous vendor. Hence this follow-up considered as non-significant.

Listedness of events burning sensation and hypoaesthesia retained as per previous assessment.

Company Remarks (Sender's Comments) :

Evaluator comment:
Causality of previously reported events retained as per previous assessment:
Burning sensation: Not related to drug and device.
Hypoaesthesia: Not related to drug and device.

Additional Information (Continuation...)

Lab Result :

Test Name	Test Date	Test Result	Normal Value
TOTAL PROSTATIC ANTIGEN	/Nov/2024		

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

1) Test Name: TOTAL PROSTATIC ANTIGEN

Result Unstructured Data (free text) : Everything was fine and normal
Test Date: /Nov/2024

Lab Comments :

1) Test Name : TOTAL PROSTATIC ANTIGEN

Lab Comments : Everything was fine and normal

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

Product-Reaction Level

Continuation Sheet for CIOMS report

1) Drug	:	Eligard® (Leuprolide acetate)
Active Substance	:	1) Leuprolide acetate
Drug Characterization	:	Suspect
Form of Admin	:	1) Injection 2) Injection
Lot Number	:	1) Unknown 2) Unknown
Daily Dose	:	(45 milligram(s), 1 in 6 Month) (45 milligram(s), 1 in 6 Month)
Route of Admin	:	1) Subcutaneous 2) Subcutaneous
Indications	:	1) Prostate cancer [10060862 - Prostate cancer]
Therapy Dates	:	1) From : 22/May/2023 To :Unknown
Action(s) Taken With Drug	:	Unknown

Causality

1) FELT AS IF HE HAD FIRE IN HIS LEGS AND THEY FELL ASLEEP (Burning sensation of lower limb - 10080423, Burning sensation - 10006784)

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

2) FELT AS IF HE HAD FIRE IN HIS LEGS AND THEY FELL ASLEEP (Numbness in leg - 10029839, Hypoaesthesia - 10020937)

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

Labeling :

1) FELT AS IF HE HAD FIRE IN HIS LEGS AND THEY FELL ASLEEP
CORE UnLabeled
2) FELT AS IF HE HAD FIRE IN HIS LEGS AND THEY FELL ASLEEP
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) FELT AS IF HE HAD FIRE IN HIS LEGS AND THEY FELL ASLEEP (Burning sensation of lower limb - 10080423, Burning sensation - 10006784)

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

2) FELT AS IF HE HAD FIRE IN HIS LEGS AND THEY FELL ASLEEP (Numbness in leg - 10029839, Hypoaesthesia - 10020937)

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

Labeling :

1) FELT AS IF HE HAD FIRE IN HIS LEGS AND THEY FELL ASLEEP
CORE
2) FELT AS IF HE HAD FIRE IN HIS LEGS AND THEY FELL ASLEEP
CORE

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

Dosage Text :

Drug 1 :Eligard®

1) 45 milligram, q 6 month

2) 45 milligram, q 6 month

Continuation Sheet for CIOMS report

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

1). Drug	:	TEOPRIN
Active Substance	:	1) BICALUTAMIDE
Form Strength	:	1) 50 Milligram
Daily Dose	:	1) 1.0 dosage form (1 dosage form, 1 in 1 Day)
Indications	:	1) Hormonal therapy [10048783 - Cancer hormonal therapy]
Dosage Text	:	1) 1 dosage form, qd

2). Drug	:	METFORMIN
Active Substance	:	1) METFORMIN
Form Strength	:	1) 100 Milligram
Daily Dose	:	1) (in 1 Day)
Indications	:	1) Diabetes [10012601 - Diabetes mellitus]
Dosage Text	:	1) UNK, qd

23. OTHER RELEVANT HISTORY (Continuation...)

2) DIABETES (10012594 , Diabetes) (Continuing : YES)

Past Therapy (ies)

Product Name	:	RADIOTHERAPY
Indication	:	Prostate cancer (10060862)
Start Date	:	
Stop Date	:	/Nov/2023