CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

GT-TOLMAR, INC.-24GT052318

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
LACH	GUATEMALA	22	May	1949	75	Male		Feb	2024

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

1) Teoprin was took late, because of which he overslept (Sleep excessive (10041000), Hypersomnia (10020765)) (08/Jan/2025 -) - Unknown
2) Felt alone (Feeling lonely (10016341), Psychiatric symptom (10061472)) (Asked but Unknown -) - Not Recovered/Not Resolved/Ongoing
3) Got sick for that reason he went to the emergency of Unicar (place) (Sickness (10040658), Illness (10080284)) (Asked but Unknown -) - Unknown
4) Not slept well because of the pain and sometimes he sleeps during the day (Sleep disturbance (10040995), Sleep disorder (10040984)) 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) (45 Milligram, Injection)(14176A; UNK; UNK)(45 Milligram, Injection)(Unknown)(45 Milligram, Injection)(Unknown)

Cont..

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

17. INDICATION(S) FOR USE

1) Prostate cancer [10060862 - Prostate cancer]

18. THERAPY DATE(S) (from/to)	19. THERAPY DURATION
1) (07/Feb/2024 - Ongoing)	

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

21. DID EVENT REAPPEAR AFTER REINTRODUCTION ☐ YES ☐ NO ☑ NA

(NA : Not Applicable)

III. CONCOMITANT DRUG(S) AND HISTORY

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

1)METFORMIN(METFORMIN)

Cont..

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

1) DIABETES (10012594, Diabetes) (//1971 -) (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
Anjan.Chatterjee@tolmar.comand+1-9702124900

Study Information
Study Name: NA
EudraCT Number:
Protocol No.: NA
Center No.:
Subject Id :

24.REPORT NULLIFIED ☐ YES ☐ NO

24b. MFR CONTROL NO.

GT-TOLMAR, INC.-24GT052318

24c. DATE RECEIVED BY MANUFACTURER

06/Aug/2025

24d. REPORT SOURCE ☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL

DATE OF THIS REPORT

14/Aug/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...)

5) Nighttime hot flashes/Hot flashes with greater intensity at night (Hot flashes (10020407), Hot flush (10060800)(/Feb/2024 -) - Not Recovered/Not Resolved/Ongoing)

6) Night sweats (Night sweats (10029410), Night sweats (10029410)(/Feb/2024 -) - Recovering/Resolving)

Event Description :

This Study report from GUATEMALA was received by Adium via Patient Support Program (reference number: GT-ADIUM-GT-0426-20240829) on 29-AUG-2024 from a Consumer/Other Non-Health Prof regarding an Elderly 75 Years old Male patient who experienced Felt alone (Feeling lonely), 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 29-AUG-2024.

The patient's medical history and current conditions included: Prostate cancer, Myocardial infarction, Infarction, Chest pain, Diabetes mellitus, Blood pressure increased, Venous occlusion.

Concomitant medications included: metformin, insulin, teoprin, desketoprofeno, desketoprofeno, Ranexa (ranolazine), clopidogrel, atenolol, irbesartan.

On 07-FEB-2024, 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 07-AUG-2024, the patient received Eligard 45 milligram, q 6 month, via Subcutaneous use for Prostate cancer (Lot numbers and Expiration dates not provided). On an unknown date, unknown amount of time after the most recent dose of Eligard, the patient felt alone, because his family did not support him. Corrective treatment was not reported. Action taken with Eligard in response to the event was Dose Not Changed. De-challenge and re-challenge were not applicable. The outcome of Feeling lonely was Not Recovered/Not Resolved.

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

On 03-SEP-2024 and 04-SEP-2024, follow-up information was received by via Patient Support Program (reference number: GT-ADIUM-GT-0426-20240829) from a Consumer/Other Non-Health Prof and sent to Tolmar on 04-SEP-2024 and 05-SEP-2024. New information included the events of hot flashes (Hot flashes) and Night sweats (Night sweats). Medical history was added.

The patient's medical history and current conditions included Hypertension, Arthritis and Vein disorder was reported.

On an unspecified date in FEB-2024, the patient experienced nighttime hot flashes and night sweats. Corrective treatment or further details were not provided. Action taken with Eligard treatment in response to the events were dose not changed, de-challenge and re-challenge were not applicable. The outcome of Hot flashes was Recovering/Resolving. The outcome of Night sweats) was Recovering/Resolving.

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

On 08-JAN-2025, follow-up information was received by Adium via Patient Support Program (reference number: GT-ADIUM-GT-0426-20240829) from a Consumer/Other Non-Health Prof and sent to Tolmar on 13-JAN-2025. New information included: Addition of non-serious events of ‘Got sick' (Sickness), ‘Not slept well because of the pain and sometimes he sleeps during the day' (Sleep disturbance) and ‘Teoprin was took late, because of which he overslept' (Sleep excessive) and added concomitant medications.

Concomitant medications included Ranexa [ranolazine] and Cloripel.

On an unspecified date, after an unspecified amount of time from most recent dose of Eligard (reported as 20 days ago) the patient got sick for which he went to the emergency, but they could not put the valves because his veins were very small and there were no valves for that type of veins, he mentioned that he was prone to have another heart attack and the patient assumed that it could be the last one, he was not tested because it had been a long time. On an unspecified date, the patient was terminated and left with medications Renaxa and Cloripel. On an unspecified date, the patient had lot of chest pain on the left side, he had not slept well at night because of the pain and sometimes he sleept during the day and he had been late in taking Teoprin 10 minutes (of the time he should take it) and it had happened 5 times, for this reason the patient decided to take Teoprin at night. On 08-JAN-2025 the patient did not take the Teoprin at the time he was supposed to take it and took it late because he overslept. Action taken with Eligard in response to the events was Dose Not Changed. De-challenge and re-challenge were not applicable. The outcome of Sickness was Unknown. The outcome of Sleep disturbance was Unknown. The outcome of Sleep excessive was Unknown.

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

On 24-MAR-2025, follow-up information was received by Adium (reference number: GT-ADIUM-GT-0426-20240829) from a Consumer/Other Non-Health Prof and sent to Tolmar on 25-MAR-2025. New information included Concomitant medications and recent dose Eligard were added.

Concomitant medications included ASPIRIN [ACETYLSALICYLIC ACID], AZACORT.

On an unknown date in FEB-2025, the patient received Eligard 45 milligram, q 6 month, via Subcutaneous use for Prostate cancer (Lot numbers and Expiration dates not provided). The patient commented that he had sleeping problems, he indicated that the cause is due to his age, illness, problems (heart) and tension, he mentioned that a doctor came to his home and gave him a Valium pill, to be able to sleep, which made the patient sleep all night and woke up on 24-MAR-2025 at 9:30 am, he referred that this made the patient did not sleep all night and woke up on 24-MAR-2025 at 9:30 am, he said that this meant that the patient did not take the medicines he was supposed to take in the morning. The patient comments that not being able to

Continuation Sheet for CIOMS report

sleep well makes him feel bad because it is difficult for him to follow the sequence and schedule of the other medicines, he mentions that the doctor who gave him the Valium pill did not tell him if he could continue taking it.

On 06-Aug-2025, follow up information was received by Adium via Patient Support Program (reference number: GT-ADIUM-GT-0426-20240829 (6)) from a Consumer (Non-Healthcare Professional) and sent to Tolmar on 07-Aug-2025. New information included: Added Eligard 45 mg dose details. Updated the verbatim of "Hot flush" from "Nighttime hot flashes" to "Nighttime hot flashes/Hot flashes with greater intensity at night" and outcome from "recovering" to "not recovered". Narrative was updated.

On 07-Feb-2024, the patient began receiving Eligard 45 milligram, every 6 month via subcutaneous use for prostate cancer (Lot numbers: 14176A; UNK; UNK and Expiration dates: Aug-2025; UNK; UNK).

On an unknown date in Jan-2025, the patient experienced hot flashes with greater intensity at night. No further details were provided.

Corrective treatment was not reported.

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

The outcome of hot flush was not recovered.

The reporter did not assess the seriousness of the event hot flush.

The reporter assesses the causality of hot flush in relationship to Eligard and Eligard Unspecified device as related.

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

Listedness of the events hypersomnia, sleep disorder, illness, hot flush, night sweats, and psychiatric symptom is retained as per previous assessment.

Company Remarks (Sender's Comments) :

Evaluator Comment (Tolmar): Causality
Hypersomnia-Not related to drug and device
Sleep disorder-Not related to drug and device
Illness-Not related to drug and device
Hot flush-Not related to drug and device
Night sweats-Related to drug and not related to device
Psychiatric symptom-Related to drug and not related to device

Causality of the events hypersomnia, sleep disorder, illness, hot flush, night sweats, and psychiatric symptom is retained as per previous assessment.

Additional Information (Continuation...)

Lab Result :

Test Name	Test Date	Test Result	Normal Value
BLOOD PRESSURE	Unknown		

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

1) Test Name: BLOOD PRESSURE

Result Unstructured Data (free text) : Notes: High

Test Date: Unknown

Lab Comments :

1) Test Name : BLOOD PRESSURE

Lab Comments : High

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
2) 45 Milligram

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		3) 45 Milligram
Form of Admin	:	1) Injection
		2) Injection
		3) Injection
Lot Number	:	1) 14176A; UNK; UNK
		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 : 07/Feb/2024 To :Continuing
		2) From : 07/Aug/2024 To :Continuing
		3) From : /Feb/2025 To :Continuing
Action(s) Taken With Drug	:	Dose not changed

Causality

1) Teoprin was took late, because of which he overslept (Sleep excessive - 10041000, Hypersomnia - 10020765)

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

2) Felt alone (Feeling lonely - 10016341, Psychiatric symptom - 10061472)

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

3) Got sick for that reason he went to the emergency of Unicar (place) (Sickness - 10040658, Illness - 10080284)

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

4) Not slept well because of the pain and sometimes he sleeps during the day (Sleep disturbance - 10040995, Sleep disorder - 10040984)

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

5) Nighttime hot flashes/Hot flashes with greater intensity at night (Hot flashes - 10020407, Hot flush - 10060800)

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

6) Night sweats (Night sweats - 10029410, Night sweats - 10029410)

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

Labeling :

1) Teoprin was took late, because of which he overslept	
CORE	UnLabeled
2) Felt alone	
CORE	UnLabeled
3) Got sick for that reason he went to the emergency of Unicar (place)	
CORE	UnLabeled
4) Not slept well because of the pain and sometimes he sleeps during the day	
CORE	UnLabeled
5) Nighttime hot flashes/Hot flashes with greater intensity at night	
CORE	Labeled
6) Night sweats	
CORE	Labeled

Continuation Sheet for CIOMS report

2) Drug : Eligard® Unspecified Device (Leuprolide acetate)
Active Substance : 1) Leuprolide acetate
Drug Characterization : Suspect
Form of Admin : 1) Injection
Route of Admin : 1) Unknown
Indications : 1) Prostate cancer [10060862 - Prostate cancer]
Action(s) Taken With Drug : Not applicable

Causality

1) Teoprin was took late, because of which he overslept (Sleep excessive - 10041000, Hypersomnia - 10020765)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

2) Felt alone (Feeling lonely - 10016341, Psychiatric symptom - 10061472)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

3) Got sick for that reason he went to the emergency of Unicar (place) (Sickness - 10040658, Illness - 10080284)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

4) Not slept well because of the pain and sometimes he sleeps during the day (Sleep disturbance - 10040995, Sleep disorder - 10040984)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

5) Nighttime hot flashes/Hot flashes with greater intensity at night (Hot flashes - 10020407, Hot flush - 10060800)
Causality as per reporter : Related
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

6) Night sweats (Night sweats - 10029410, Night sweats - 10029410)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) Teoprin was took late, because of which he overslept
CORE
2) Felt alone
CORE
3) Got sick for that reason he went to the emergency of Unicar (place)
CORE
4) Not slept well because of the pain and sometimes he sleeps during the day
CORE
5) Nighttime hot flashes/Hot flashes with greater intensity at night
CORE
6) Night sweats
CORE

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

Continuation Sheet for CIOMS report

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

1). Drug	:	METFORMIN
Active Substance	:	1) METFORMIN
Form Strength	:	
Daily Dose	:	1) 850 (850, 1 in 1 Day)
Route of Admin	:	1) Unknown
Indications	:	1) Diabetes [10012594 - Diabetes]
Dosage Text	:	1) Unit Dose : 850 Daily Dose : 850 850 UNK, evening

2). Drug	:	INSULIN NOS
Active Substance	:	1) INSULIN NOS
Form Strength	:	
Daily Dose	:	1) (30 international unit(s))
Route of Admin	:	1) Unknown
Indications	:	1) Diabetes [10012594 - Diabetes]
Dosage Text	:	1) 30 international unit

3). Drug	:	TEOPRIN
Active Substance	:	1) BICALUTAMIDE
Form Strength	:	
Daily Dose	:	1) 50 milligram(s) (50 milligram(s), 1 in 1 Day)
Route of Admin	:	1) Unknown
Indications	:	1) Prostate cancer [10060862 - Prostate cancer]
Dosage Text	:	1) 50 milligram, qd

4). Drug	:	DESKETOPROFENO
Active Substance	:	1) DEXKETOPROFEN TROMETAMOL
Form Strength	:	1) 25 Milligram
Form of Admin	:	1) Pill
Daily Dose	:	1) (2 dosage form)
Route of Admin	:	1) Unknown
Indications	:	1) Pain chest [10033387 - Pain chest]
Dosage Text	:	1) 2 dosage form

5). Drug	:	DESKETOPROFENO
Active Substance	:	1) DEXKETOPROFEN TROMETAMOL
Form Strength	:	1) 15 Milligram
Form of Admin	:	1) Injection
Daily Dose	:	1) (15 milligram(s))
Route of Admin	:	1) Unknown
Indications	:	1) Pain chest [10033387 - Pain chest]
Dosage Text	:	1) 15 milligram, prn

6). Drug	:	RANEXA [RANOLAZINE]
Active Substance	:	1) RANOLAZINE
Form Strength	:	
Daily Dose	:	1) 1000 milligram(s) (500 milligram(s), 2 in 1 Day)
Route of Admin	:	1) Unknown
Indications	:	1) Heart attack [10019250 - Heart attack]
		2) Clogged veins [10058990 - Venous occlusion]
Dosage Text	:	1) 500 milligram, bid

7). Drug	:	CLOPIDOGREL
Active Substance	:	1) CLOPIDOGREL
Form Strength	:	1) 75 Milligram
Daily Dose	:	1) 75 milligram(s) (75 milligram(s), 1 in 1 Day)
Route of Admin	:	1) Unknown
Indications	:	1) Infarction [10061216 - Infarction]
		2) Clogged veins [10058990 - Venous occlusion]

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Dosage Text	:	1) 75 milligram, evening

8). Drug	:	ATENOLOL
Active Substance	:	1) ATENOLOL
Form Strength	:	1) 100 Milligram
Daily Dose	:	1) 50 milligram(s) (50 milligram(s), 1 in 1 Day)
Route of Admin	:	1) Unknown
Indications	:	1) Infarction [10061216 - Infarction]
Dosage Text	:	1) 50 milligram, morning

9). Drug	:	IRBESARTAN
Active Substance	:	1) IRBESARTAN
Form Strength	:	
Form of Admin	:	1) Tablet
Daily Dose	:	1) 1 dosage form (1 dosage form, 1 in 1 Day)
Route of Admin	:	1) Unknown
Indications	:	1) High blood pressure [10005747 - Blood pressure high]
Dosage Text	:	1) 1 dosage form, morning

10). Drug	:	OTHER THERAPEUTIC PRODUCTS
Form Strength	:	
Route of Admin	:	1) Unknown
Indications	:	1) Heart disorder [10019277 - Heart disorder]
Dosage Text	:	1) UNK

11). Drug	:	ASPIRIN [ACETYLSALICYLIC ACID]
Active Substance	:	1) ACETYLSALICYLIC ACID
Form Strength	:	
Route of Admin	:	1) Unknown
Indications	:	1) thin his blood [10053468 - Anticoagulant therapy]

12). Drug	:	AZACORT
Active Substance	:	1) DEFLAZACORT
Form Strength	:	
Daily Dose	:	1)
Route of Admin	:	1) Unknown
Indications	:	1) feels a lot of pain in his heart [10054231 - Cardiac pain]
Dosage Text	:	1) UNK, prn

23. OTHER RELEVANT HISTORY (Continuation...)

2) HEART ATTACK (10019250 , Heart attack) (//2022 -) (Continuing : NO)

3) VERY SMALL VEINS IN THE HEART (10047184 , Vein disorder) (/Jan/2024 -) (Continuing : YES)

4) PROSTATE CANCER (10060862 , Prostate cancer) (Asked but Unknown -) (Continuing : YES)

5) PAIN CHEST (10033387 , Pain chest) (Asked but Unknown -) (Continuing : YES)

6) HIGH BLOOD PRESSURE (10005747 , Blood pressure high) (Asked but Unknown -) (Continuing : YES)

7) INFARCTION (10061216 , Infarction) (Asked but Unknown -) (Continuing : YES)

8) TWO CLOGGED VEINS (10058990 , Venous occlusion) (Asked but Unknown -) (Continuing : YES)

9) HYPERTENSION (10020772 , Hypertension) (Asked but Unknown -) (Continuing : YES)

10) KNEE INFLAMMATION (10023217 , Joint inflammation) (Asked but Unknown -) (Continuing : YES)