

SUSPECT ADVERSE REACTION REPORT	
DO-TOLMAR, INC.-23DO041705	

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 <input type="checkbox"/> PATIENT DIED <input type="checkbox"/> LIFE THREATENING <input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION <input type="checkbox"/> RESULTS IN PERSISTENCE OR SIGNIFICANT DISABILITY/INCAPACITY <input type="checkbox"/> CONGENITAL ANOMALY <input checked="" type="checkbox"/> OTHER MEDICALLY IMPORTANT CONDITION
HJBCS	DOMINICAN	Day	Month	Year	66	Male	Day	Month	Year	
Cont..		24	May	1957					2023	

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

1) patient was clogged and could not urinate (Urinary obstruction unspecified (10046548), Urinary tract obstruction (10061574))
Unknown

2) he feels hot / hot inside (Feeling hot (10016334), Feeling hot (10016334))
(//2023 -) - Not Recovered/Not Resolved/Ongoing

3) got thirsty (Thirst (10043458), Thirst (10043458))
(//2023 -) - Not Recovered/Not Resolved/Ongoing

4) in November 2023 it was his turn to apply Eligard medication, but he did not apply it because the urologist indicated that the results of his total PSA (prostate antigen) test were quite good (Therapy cessation by healthcare provider (10072906), Therapy cessation (10065154))
(/Nov/2023 - /Apr/2024) - Recovered/Resolved

Cont..

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) 1) Eligard® (Leuprolide acetate, Leuprolide acetate) (Suspect) (45 Milligram, Injection) (Unknown) (45 Milligram, Injection) (Unknown) (UNK)		20. DID EVENT ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA 21. DID EVENT REAPPEAR AFTER REINTRODUCTION <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA (NA : Not Applicable)	
15. DAILY DOSE(S) 1) (45 milligram(s), 1 in 6 Month) 2) (45 milligram(s), 1 in 6 Month)			
16. ROUTE(S) OF ADMINISTRATION 1) Subcutaneous 2) Subcutaneous			
17. INDICATION(S) FOR USE 1) Prostate cancer [10060862 - Prostate cancer]			
18. THERAPY DATE(S) (from/to) 1) (15/May/2023 - /Nov/2024)		19. THERAPY DURATION	

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction) 1) JANUMET (METFORMIN HYDROCHLORIDE)	Cont..
23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergies, pregnancy with last month of period, etc.) 1) PROSTATE SURGERY (10073343, Prostate surgery) (//2002 -) (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.com and +1--9702124900		Study Information Study Name: NA EudraCT Number: Protocol No.: NA Center No.: Subject Id :	
24. REPORT NULLIFIED <input type="checkbox"/> YES <input type="checkbox"/> NO	24b. MFR CONTROL NO. DO-TOLMAR, INC.-23DO041705		
24c. DATE RECEIVED BY MANUFACTURER 25/Jun/2025	24d. REPORT SOURCE <input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL		
DATE OF THIS REPORT 02/Jul/2025	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> 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...)

5) Treatment discontinuation due to improvement (Therapy cessation (10065154), Therapy cessation (10065154)/(Nov/2024 -) - Unknown)

6) uncomfortable and annoying (Feeling irritated (10016337), Irritability (10022998) - Unknown)

7) Sweating all over his body every hour / still sweated; he did not suffer from this sweating symptom until he applied Eligard's medication / sweats too much (Sweating (10042661), Hyperhidrosis (10020642))/(2023 -) - Not Recovered/Not Resolved/Ongoing)

Event Description :

This Study report from DOMINICAN REPUBLIC was received by Adium (reference number: DO-0165-20230628) via Patient Support Program "ASOFARMA A TU LADO" on 27-JUN-2023 from a Consumer regarding an Elderly 66 Years old Male patient who experienced Sweating all over his body every hour (Sweating) 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 28-JUN-2023.

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

Concomitant medications were not reported.

On an unknown date, the patient began receiving Eligard 45 milligram, q 6 month, via Subcutaneous use for Prostate cancer (Batch details were not provided). On an unknown date, after the most recent dose of Eligard, the patient experienced Sweating all over his body every hour. Corrective treatment nor further details were provided. Action taken with Eligard in response to the event was Dose Not Changed. De-challenge was Not applicable, and re-challenge was Not applicable. The outcome of Sweating was Not Recovered/Not Resolved.

The reporter did not assess the seriousness or causality of the event(s) in relationship to Eligard.

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

On 04-JAN-2024, follow-up information was received by Adium via Patient Support Program "ASOFARMA A TU LADO" (reference number: DO-0165-20230628) from the Consumer and sent to Tolmar on 04-JAN-2024. Added non-serious events of "he feels hot (Feeling hot)", "got thirsty (Thirst)" and "in November 2023 it was his turn to apply Eligard medication, but he did not apply it because the urologist indicated that the results of his total PSA (prostate antigen) test were quite good (Therapy cessation by healthcare provider)". Added current conditions, procedure, Eligard start date and stop date, lab data and concomitant medications. Updated action taken. Updated verbatim from "Sweating all over his body every hour" to "Sweating all over his body every hour / still sweated; he did not suffer from this sweating symptom until he applied Eligard's medication" and its reporter causality.

Current conditions included Diabetes mellitus and Hypertension. Procedures included Prostatic operation.

Concomitant medications included JANUMET (HYDROCHLOROTHIAZIDE, LOSARTAN POTASSIUM) and LOSACOR D (HYDROCHLOROTHIAZIDE, LOSARTAN POTASSIUM).

In April 2002 he underwent prostate surgery, not remembered the name, but his prostate antigen was not low enough because it was 3 ng/ml and it had to be below 1 ng/ml, so he was given Eligard 45 mg and in the first dose his prostate antigen was below 1 ng/ml. In 2023 until Nov 2023, the patient received Eligard 45 milligram, q 6 month, via Subcutaneous use, for Prostate cancer (Lot details unknown). Moreover, in November 2023 it was his turn to apply Eligard medication, but he did not apply it because the urologist indicated that the results of his total PSA (prostate antigen) test were quite good because they were low of 1 or less 1 mg/ml for such reason doctor considered that it was not necessary to place the Eligard medication; the result was satisfactory in the first application of the treatment, because having the PSA (prostate antigen) in 3.5 ng/ ml, he lowered it below 1 ng/ml. When the person assigned by Asofarma applied the first application of the Eligard medication in 2023, he had a side effect of sweating and even if he had air conditioning, was standing still, even if he did not feel nervous, was sleeping, was lying down, was in the air, he still sweated for 3 minutes and then it disappeared. The consumer referred that he did not suffer from this sweating symptom until he applied Eligard's medication. The doctor told him that with the injection of the Eligard medication, no patient had presented this sweating symptom, he was told that he had only presented the symptom of suffocation as heat; the patient assumed that the patient did not receive the medication correctly because he felt hot and sweats, for this reason the doctor told that it was very rare that he had this effect and no patient who had gone to consult with him had presented this symptom. The consumer mentioned that he sweated even if he had the air conditioning, and currently continued with the sweating symptom, the patient expected that after the 6 months that he completed in November 2023 of having applied the first dose of Eligard which was approximately in April or March (not remembered well), the symptoms would disappear and would no longer continue with sweating; nevertheless the effect persisted. Because currently he left his office to get some air and he got thirsty, he commented that on January 03, 2024 he measured his blood sugar with a home meter and it was 87 mg/dl and it was fine because he has it under control because sometimes he had it at 100 mg/dl, 105 mg/dl or 90 mg/dl, so he was under control; for this reason he did not want to take any medication before visiting a doctor. 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 Feeling hot was Unknown. The outcome of Thirst was Unknown. The outcome of Therapy cessation by healthcare provider was Unknown. The outcome of Sweating was Not Recovered/Not Resolved.

Relevant test results included:

Continuation Sheet for CIOMS report

Unknown date: Blood glucose 100 milligram per decilitre (Ref range: Not provided)
 Unknown date: Blood glucose 105 milligram per decilitre (Ref range: Not provided)
 Unknown date: Blood glucose 90 milligram per decilitre (Ref range: Not provided)
 03-JAN-2024: Blood glucose 87 milligram per decilitre (Ref range: Not provided)
 2023: Prostatic specific antigen: low of 1 or less than 1 mg/ml (Ref range: Not provided)
 2023: Prostatic specific antigen 3.5 nanogram per milliliter (Ref range: Not provided)
 2023: Prostatic specific antigen 1 nanogram per milliliter (Ref range: Not provided)
 APR-2002: Prostatic specific antigen 3 nanogram per milliliter (Ref range: UNK-1 nanogram per milliliter)

The reporter did not assess the seriousness of Sweating and assessed the causality in relationship to Eligard as Related. The reporter did not assess the seriousness or causality of the remaining events in relationship to Eligard.

On 10-JAN-2024, follow-up information was received by Adium (reference number: DO-0165-20230628) from a Consumer and sent to Tolmar on 11-JAN-2024. New information included: event course details of Sweating.

It was reported that the patient did not suffer from asphyxia as heat, he only presented the symptom of sweating that lasts from 2 to 3 minutes even if he was with air conditioning or if he uses a fan, he always presented the symptom 24/7, he woke up 1 or 2 times at night to remove the sweat with a fan. In Mar-2024 the patient will have an appointment with his treating physician to have his PSA tests done again, to verify if he continues with Eligard treatment. Corrective treatment was not reported. Action taken with Eligard in response to the event was Unknown. De-challenge was not applicable, and re-challenge was not applicable. The outcome of Sweating was Not Recovered/Not Resolved.

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

On 07-JUN-2024, follow-up information was received by Adium (reference number: DO-0165-20230628) from a Consumer/Other Non-Health Prof and sent to Tolmar on 10-JUN-2024. New information included details regarding a new event of hot inside (Feeling hot), updated verbatim from "he feels hot" to "he feels hot / hot inside", updated outcome from Unknown to Not Recovered/Not Resolved, new event of got thirsty (Thirst), updated outcome from Unknown to Not Recovered/Not Resolved, new event of Sweating all over his body every hour / still sweated; he did not suffer from this sweating symptom until he applied Eligard's medication / sweats too much (Sweating), updated verbatim from "Sweating all over his body every hour / still sweated; he did not suffer from this sweating symptom until he applied Eligard's medication" to "Sweating all over his body every hour / still sweated; he did not suffer from this sweating symptom until he applied Eligard's medication / sweats too much" details regarding the event uncomfortable and annoying (Feeling irritated), and the medically significant event of patient was clogged and could not urinate (Urinary obstruction unspecified); laboratory tests, radiotherapy as concomitant medication, updated procedures and most recent Eligard dose.

The patient's medical history and current conditions included Transurethral prostatectomy as procedure.

Concomitant medications included radiotherapy.

On APR-2024, the patient received Eligard 45 milligram, q 6 month via Subcutaneous use (Lot numbers and Expiration dates were not provided). On an unspecified date, after the most recent Eligard dose, the Eligard medication caused side effects, the patient was uncomfortable and annoying, because the patient sweated too much, it lasted 3 or 4 minutes, but in that time it made the patient thirsty and the patient must drink water, it was reported that it was a tremendous sweat. Moreover, the patient felt like hot inside and the sweat came at once, and had to use a fan for the sweat and heat, even if it lasted for only 3 or 4 minutes. Reportedly, when the patient was in meetings or was working and sweating occurred, people assumed that the patient was ill or nervous, because the sweat was copious, these effects occurred 24/7 every day, even if patient had air conditioning at night at home and in office, if he was in a cold place, the symptoms appeared but less frequently, but if the patient was somewhere outdoors, the symptoms of sweating and heat appeared more frequently, or when the temperature raised. It was reported that the patient had a TURP performed because of the cancer and because patient was clogged and could not urinate.

Corrective treatment was not reported.

Action taken with Eligard in response to the events was Dose Not Changed. De-challenge was not applicable, and re-challenge was not applicable.

The outcome of Urinary obstruction unspecified was Unknown. The outcome of Feeling hot was Not Recovered/Not Resolved.

The outcome of Thirst was Not Recovered/Not Resolved. The outcome of Feeling irritated was Unknown. The outcome of Sweating was Not Recovered/Not Resolved.

Relevant test results included:

Unknown date: Prostatic specific antigen: 9 ng/ml (Ref range: Not provided). Started with a PSA percentage of 9 ng/ml, after the patient underwent radiotherapy and TUR surgery.

After surgery: Prostatic specific antigen 8 ng/ml (Ref range: Not provided). PSA at 8 ng/ml.

Unknown date: Prostatic specific antigen 3 ng/ml (Ref range: Not provided). The PSA percentage dropped to 3ng/ml, that was when the patient started with the Eligard medication.

After the first application in February or March 2023: Prostatic specific antigen (Ref range: Not provided). PSA was at the level that the patient should have in November 2023.

April 2024: Prostatic specific antigen less than 1 ng/ml (Ref range: Not provided). The analysis was carried out again and it was verified that the patient's PSA was less than 1 ng/ml.

Unknown date: Blood testosterone (Ref range: Not provided). testosterone was high.

Continuation Sheet for CIOMS report

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

ON 14-JUN-2024, Upon internal review: Urinary tract obstruction was upgraded to serious medically significant. No further changes were performed.

On 25-Jun-2025, follow-up information was received by Adium (reference number: DO-0165-20230628 (4)) and additional information was received on (reference number: DO-0165-20230628 (5)) 26-Jun-2025 from a consumer (non-healthcare professional) and sent to Tolmar on 26-JUN-2025 and 27-Jun-2025. New information included: Updated Eligard dose details and added a new non-serious event of "Treatment discontinuation due to improvement" (Therapy cessation). Updated action taken from 'dose not changed' to 'unknown'. Patient's weight was reported as 123kg. Outcome of previously reported event (Therapy cessation) was corrected from 'unknown' (captured by previous vendor) to 'resolved' on April-2024. Narrative was updated.

On 15-May-2023, 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 it was reported that the patient did not have prostate cancer.

On an unknown date in Nov-2024, the patient discontinued the treatment due to improvement.

No further information was provided.

Corrective treatment was not reported.

Action taken with Eligard in response to the event was unknown. 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 assessed the causality of therapy cessation in relationship to Eligard and Eligard Unspecified device as related.

No further query was done.

Listedness of previously reported events were retained as previously assessed.

therapy cessation >Eligard® >unlisted as per CCDS Eligard®> 7-Nov-2024
therapy cessation> Eligard® >unlisted as per Canadian Monograph Eligard®> 2-Apr-2025
therapy cessation> Eligard®>unlisted as per USPI Eligard®>Feb-2025
therapy cessation> Eligard® Unspecified Device>unlisted as per USPI Eligard®>Feb-2025

Company Remarks (Sender's Comments) :

Evaluator Comment (Tolmar): This 66 years old male patient had Urinary tract obstruction (patient was clogged and could not urinate), Feeling hot (he feels hot / hot inside), Thirst (got thirsty), Therapy cessation (in November 2023 it was his turn to apply Eligard medication, but he did not apply it because the urologist indicated that the results of his total PSA (prostate antigen) test were quite good), Irritability (uncomfortable and annoying) and Hyperhidrosis (Sweating all over his body every hour / still sweated; he did not suffer from this sweating symptom until he applied Eligard's medication / sweats too much) during Eligard (Leuprolide acetate) 45 milligram therapy for Prostate cancer. Tolmar assessed Urinary tract obstruction as medically significant based on its nature and reported intervention and the remaining events as non-serious since there was no immediate jeopardy to patient and they did not meet ICH seriousness criteria. Hyperhidrosis was assessed as related to Eligard drug (unrelated to device) based on temporal relation and known safety profile of the drug for hyperhidrosis. All other events were assessed as not related to Eligard (drug and device) based on the etiology of the events, known safety profile of the drug and inconsistency with drug properties. Urinary tract obstruction was attributed to prostate malignancy based on the treatment with TURP. Therapy cessation was due to human action.

FU added event of therapy cessation (treatment discontinuation due to improvement). Tolmar assessed the reported event as non-serious since it did not meet the ICH seriousness criteria. The causality of event therapy cessation was assessed as not related to suspect Eligard(drug and device) as it occurred due to human action and not due to drug.

Additional Information (Continuation...)

Lab Result :

Test Name	Test Date	Test Result	Normal Value
BLOOD SUGAR	03/Jan/2024	87 milligram per decilitre	

BLOOD SUGAR	Unknown	100 milligram per decilitre	
BLOOD SUGAR	Unknown	105 milligram per decilitre	
BLOOD SUGAR	Unknown	90 milligram per decilitre	
PSA	/Apr/2002	3 nanogram per milliliter	- 1
PSA	//2023		
PSA	//2023	3.5 nanogram per milliliter	
PSA	//2023	1 nanogram per milliliter	
PSA	//2023		- 1
PSA	Unknown		
TESTOSTERONE LEVELS	//2023		

1) Drug	: Eligard® (Leuprolide acetate)
Active Substance	: 1) Leuprolide acetate
Drug Characterization	: Suspect
Form Strength	: 1) 45 Milligram
	2) 45 Milligram
Form of Admin	: 1) Injection
	2) Injection

Continuation Sheet for CIOMS report

Lot Number : 3) Injection
 : 1) Unknown
 : 2) Unknown
 : 3) UNK
 Daily Dose : (45 milligram(s), 1 in 6 Month)
 : (45 milligram(s), 1 in 6 Month)
 : 3) 0.25 milligram(s) (45 milligram(s), 1 in 6 Month)
 Route of Admin : 1) Subcutaneous
 : 2) Subcutaneous
 : 3) Unknown
 Indications : 1) Prostate cancer [10060862 - Prostate cancer]
 Therapy Dates : 1) From : 15/May/2023 To :/Nov/2024
 : 2) From : /Apr/2024 To :Unknown
 : 3) From : /Nov/2024 To :Unknown
 Action(s) Taken With Drug : Unknown

Causality

- 1) patient was clogged and could not urinate (Urinary obstruction unspecified - 10046548, Urinary tract obstruction - 10061574)
 - Causality as per reporter : Not Reported
 - Causality as per Mfr : Not Related
 - DeChallenge : Not applicable
 - ReChallenge : Not Applicable
- 2) he feels hot / hot inside (Feeling hot - 10016334, Feeling hot - 10016334)
 - Causality as per reporter : Not Reported
 - Causality as per Mfr : Not Related
 - DeChallenge : Not applicable
 - ReChallenge : Not Applicable
- 3) got thirsty (Thirst - 10043458, Thirst - 10043458)
 - Causality as per reporter : Not Reported
 - Causality as per Mfr : Not Related
 - DeChallenge : Not applicable
 - ReChallenge : Not Applicable
- 4) in November 2023 it was his turn to apply Eligard medication, but he did not apply it because the urologist indicated that the results of his total PSA (prostate antigen) test were quite good (Therapy cessation by healthcare provider - 10072906, Therapy cessation - 10065154)
 - Causality as per reporter : Not Reported
 - Causality as per Mfr : Not Related
 - DeChallenge : Not applicable
 - ReChallenge : Not Applicable
- 5) Treatment discontinuation due to improvement (Therapy cessation - 10065154, Therapy cessation - 10065154)
 - Causality as per reporter : Related
 - Causality as per Mfr : Not Related
 - DeChallenge : Not applicable
 - ReChallenge : Not Applicable
- 6) uncomfortable and annoying (Feeling irritated - 10016337, Irritability - 10022998)
 - Causality as per reporter : Not Reported
 - Causality as per Mfr : Not Related
 - DeChallenge : Not applicable
 - ReChallenge : Not Applicable
- 7) Sweating all over his body every hour / still sweated; he did not suffer from this sweating symptom until he applied Eligard's medication / sweats too much (Sweating - 10042661, Hyperhidrosis - 10020642)
 - Causality as per reporter : Related
 - Causality as per Mfr : Related
 - DeChallenge : Not applicable
 - ReChallenge : Not Applicable

Labeling :

- 1) patient was clogged and could not urinate
CORE UnLabeled
- 2) he feels hot / hot inside
CORE UnLabeled
- 3) got thirsty
CORE UnLabeled
- 4) in November 2023 it was his turn to apply Eligard medication, but he did not apply it because the urologist indicated that the results of his total PSA (prostate antigen) test were quite good
CORE UnLabeled

Continuation Sheet for CIOMS report

- 5) Treatment discontinuation due to improvement
CORE UnLabeled
- 6) uncomfortable and annoying
CORE UnLabeled
- 7) Sweating all over his body every hour / still sweated; he did not suffer from this sweating symptom until he applied Eligard's medication / sweats too much
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) patient was clogged and could not urinate (Urinary obstruction unspecified - 10046548, Urinary tract obstruction - 10061574)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
- 2) he feels hot / hot inside (Feeling hot - 10016334, Feeling hot - 10016334)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
- 3) got thirsty (Thirst - 10043458, Thirst - 10043458)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
- 4) in November 2023 it was his turn to apply Eligard medication, but he did not apply it because the urologist indicated that the results of his total PSA (prostate antigen) test were quite good (Therapy cessation by healthcare provider - 10072906, Therapy cessation - 10065154)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
- 5) Treatment discontinuation due to improvement (Therapy cessation - 10065154, Therapy cessation - 10065154)
Causality as per reporter : Related
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
- 6) uncomfortable and annoying (Feeling irritated - 10016337, Irritability - 10022998)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
- 7) Sweating all over his body every hour / still sweated; he did not suffer from this sweating symptom until he applied Eligard's medication / sweats too much (Sweating - 10042661, Hyperhidrosis - 10020642)
Causality as per reporter : Related
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

- 1) patient was clogged and could not urinate
CORE
- 2) he feels hot / hot inside
CORE
- 3) got thirsty
CORE
- 4) in November 2023 it was his turn to apply Eligard medication, but he did not apply it because the urologist indicated that the results of his total PSA (prostate antigen) test were quite good
CORE
- 5) Treatment discontinuation due to improvement
CORE

Continuation Sheet for CIOMS report

6) uncomfortable and annoying

CORE

7) Sweating all over his body every hour / still sweated; he did not suffer from this sweating symptom until he applied Eligard's medication / sweats too much

CORE

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

Dosage Text :

Drug 1 :Eligard®

1) 45 milligram, q 6 month

2) 45 milligram, q 6 month

Drug 2 :Eligard® Unspecified Device

1) UNK

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

1). Drug : JANUMET
 Active Substance : 1) METFORMIN HYDROCHLORIDE
 2) SITAGLIPTIN PHOSPHATE MONOHYDRATE

Form Strength :
 Route of Admin : 1) Unknown
 Indications : 1) diabetes [10012594 - Diabetes]
 Dosage Text : 1) 50 mg/ 1000 mg

2). Drug : LOSACOR D
 Active Substance : 1) HYDROCHLOROTHIAZIDE
 2) LOSARTAN POTASSIUM
 Form Strength :
 Route of Admin : 1) Unknown
 Indications : 1) Blood pressure high [10005747 - Blood pressure high]
 Dosage Text : 1) 100 mg

3). Drug : OTHER THERAPEUTIC PRODUCTS
 Form Strength :
 Route of Admin : 1) Unknown
 Indications : 1) Radiotherapy [10037794 - Radiotherapy]

23. OTHER RELEVANT HISTORY (Continuation...)

2) PROSTATE CANCER (10060862 , Prostate cancer) (//2023 -) (Continuing : NO)

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

4) BLOOD PRESSURE HIGH (10005747 , Blood pressure high) (Continuing : YES)

5) TUR SURGERY (10045182 , TURP) (Continuing : NO)