

SUSPECT ADVERSE REACTION REPORT												
	GT-TOLMAR, INC.-23GT044301											

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) C-G	1a. COUNTRY GUATEMALA	2. DATE OF BIRTH			2a. AGE Years 61	3. SEX Male	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day 25	Month Nov	Year 1961			Day 25	Month Sep	Year 2023	
7+13 DESCRIBE REACTION(S) (including relevant tests/lab data)										

1) Left knee thrombosis (Thrombosis (10043607), Thrombosis (10043607))
Unknown

2) Unable to walk due to pain in left knee and is on a wheelchair due to it (Walking difficulty (10047810), Gait disturbance (10017577))
Not Recovered/Not Resolved/Ongoing

3) PROSTATE CANCER METASTASIS IN THE BONES; ONE MONTH AGO THE CANCER SPREAD TO HIS BONES / PROSTATE CANCER METASTASIZED IN HIS BONES (Bone metastases (10005993), Metastases to bone (10027452))
(25/Sep/2023 -) - Not Recovered/Not Resolved/Ongoing

4) Lack of sleep or oversleeping (Sleep disorder (10040984), Sleep disorder (10040984))
Not Recovered/Not Resolved/Ongoing

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)		20. DID EVENT ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
1) Eligard (Leuprolide acetate, Leuprolide acetate) (Suspect) (Injection)(Unknown)(Unknown)		
Cont..		
15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION	21. DID EVENT REAPPEAR AFTER REINTRODUCTION <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA (NA : Not Applicable)
1) (22.5 milligram(s), 1 in 3 Month)	1) Subcutaneous	
2) (22.5 milligram(s), 1 in 3 Month)	2) Subcutaneous	
Cont..		
17. INDICATION(S) FOR USE		Cont..
1) Prostate cancer [10060862 - Prostate cancer]		
Cont..		
18. THERAPY DATE(S) (from/to)	19. THERAPY DURATION	
1) (24/Jan/2023 -)		

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)	Cont..
1) Chemotherapy(OTHER THERAPEUTIC PRODUCTS)	
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		Study Information Study Name: NA EudraCT Number: Protocol No.: NA Center No.: Subject Id :
Name : Tolmar, Inc 701 Centre Avenue Fort Collins, CO, 80526, UNITED STATES OF AMERICA debbie.maierhofer@tolmar.comand+1-4129158447		
24. REPORT NULLIFIED	24b. MFR CONTROL NO.	
<input type="checkbox"/> YES <input type="checkbox"/> NO	GT-TOLMAR, INC.-23GT044301	
24c. DATE RECEIVED BY MANUFACTURER	24d. REPORT SOURCE	
06/May/2025	<input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL	
DATE OF THIS REPORT	25a. REPORT TYPE	
17/May/2025	<input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP	

= Continuation attached sheet(s)..

Continuation Sheet for CIOMS report

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

5) Anxiety (Anxiety (10002855), Anxiety (10002855))/(Dec/2023 -) - Recovered/Resolved)

6) desperation (Feeling of despair (10016344), Feeling of despair (10016344))/(Dec/2023 -) - Recovered/Resolved)

7) HIS HAIR BEGAN TO FALL OUT (ALOPECIA) (Hair loss (10019045), Alopecia (10001760))/(Nov/2023 -) - Not Recovered/Not Resolved/Ongoing)

8) Left knee pain (Arthralgia (10003239), Arthralgia (10003239))/(Feb/2025 -) - Not Recovered/Not Resolved/Ongoing)

9) Tiredness (Tiredness (10043890), Fatigue (10016256) - Not Recovered/Not Resolved/Ongoing)

Event Description :

This Study report from GUATEMALA was received by Adium via Patient Support Program "ASOFARMA A TU LADO" (reference number: GT-ADIUM-GT-0902-20231025) on 25-OCT-2023, with additional information on 29-OCT-2023 (Same reference number), from a Consumer regarding a 61 Years old Male patient who experienced prostate cancer metastasis in the bones; one month ago the cancer spread to his bones (Bone metastases) during Eligard (Leuprolide acetate) 22.5 milligram therapy for Prostate cancer. The needle component of the constituent device was not identified in the report. The reports were sent to Tolmar on 26-OCT-2023 and 30-OCT-2023, respectively.

The patient's medical history was not reported. Current conditions included Prostate cancer.

Concomitant medications were not reported.

On 25-JAN-2023, the patient began receiving Eligard 22.5 milligram, q 3 month, via Subcutaneous use, for Prostate cancer (Lot details unknown). Reportedly, since 25 Sep 2023, the patient started receiving radiotherapy for inflammation in the bones, because of prostate cancer metastasis in the bones, he had received 5 radiotherapies in the patella and shoulder. It was explained that one month ago the cancer spread to his bones making it difficult for him to walk (September 25, 2023) and he was currently undergoing radiotherapy treatment. On October 25, 2023 he was indicated to receive the sixth radiotherapy in the spine. The medication used according to medical order was Kodone for pain. He did not stop Eligard treatment, last application was on October 25, 2023. As mentioned, on 25-OCT-2023, the patient received the latest dose of Eligard 22.5 milligram, q 3 month, via Subcutaneous use, for Prostate cancer (Lot details unknown). Corrective treatment included RADIOTHERAPY and OTHER THERAPEUTIC PRODUCTS (Kodone). Action taken with Eligard in response to the event was Dose Not Changed. De-challenge and re-challenge were not applicable. The outcome of Bone metastases was Not Recovered/Not Resolved.

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

On 09-NOV-2023, follow-up information was received by Adium via Patient Support Program "ASOFARMA A TU LADO" (reference number: GT-ADIUM-GT-0902-20231025) from the Consumer and sent to Tolmar on 10-NOV-2023. Added non-serious event of "his hair began to fall out (alopecia) (Hair loss)", lab data and "OTHER THERAPEUTIC PRODUCTS (treatments for prostate cancer)" as co-suspect. Updated verbatim from "prostate cancer metastasis in the bones; one month ago the cancer spread to his bones" to "prostate cancer metastasis in the bones; one month ago the cancer spread to his bones / prostate cancer metastasized in his bones".

Reportedly, 4 weeks ago (approximately in Oct 2023), the patient started with radiotherapies, he received them in the part of the head in the left occipital (head and neck radiotherapy), spine (spine radiotherapy) and knees (bone radiotherapy); the last radiotherapy that was performed was on November 06, 2023. The patient was prescribed the radiotherapies because 1 month and 20 days ago (onset previously reported as 25 Sep 2023), the doctor performed a scintigraphy test and when checking his results, he detected that the prostate cancer metastasized in his bones. Patient took Kodone 7.5 mg 4 capsules every 8 hours for pain, but the doctor told him that he had to lower the dose because it was a medication that could become addictive to the organism. Moreover, the consumer informed that 8 days ago (Nov 2023) his hair began to fall out (alopecia), this was due to the treatments he had undergone for prostate cancer. Corrective treatment was not reported. Action taken with Eligard in response to the events was Dose Not Changed. De-challenge and re-challenge were not applicable. The outcome of Bone metastases was Not Recovered/Not Resolved. The outcome of Hair loss was Not Recovered/Not Resolved.

Relevant test results included:

25-SEP-2023: Radioisotope scan: prostate cancer metastasized in his bones (Ref range: Not provided)

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

On 11-FEB-2025, follow-up information was received by Adium via Patient Support Program ASOFARMA A TU LADO (reference number: GT-ADIUM-GT-0902-20231025) from a Consumer/Other Non-Health Prof and sent to Tolmar on 12-FEB-2025. New information included: Added suspect product (Xtandi) details, Concomitant medication and clinical course details. Xtandi (Enzalutamide) was also considered as suspect.

Concomitant medications included Other Therapeutic Products (chemotherapies).

Reportedly, two months ago the physician suspended Enzalutamide because it was no longer effective, so the patient received chemotherapy. The patient had received two treatments so far and was scheduled to complete a total of six. Afterward, the patient would rest for three months and receive another six chemotherapies. In the first phase, the patient received nine chemotherapies.

Continuation Sheet for CIOMS report

On 10-MAR-2025, follow-up information was received by Adium patient support program (reference number: GT-ADIUM-GT-0902-20231025) from a Consumer/Other Non-Health Prof and sent to Tolmar on 11-MAR-2025. New information included: Added new dose of Eligard and concomitant (chemotherapy). Updated the Action taken for the Eligard 22.5 milligram to Unknown.

Reportedly, the patient's oncologist prescribed a total of 9 chemotherapies. On an unspecified date in FEB-2025, the patient was started on Eligard 45 milligram, unknown frequency, via Subcutaneous use, for prostate cancer (Lot number and expiration date details were not provided). Patient was no longer on Eligard 22.5mg. On 03-MAR-2025, the patient underwent his third chemotherapy and he had already felt the improvement. At the beginning of APR-2025 the fourth chemotherapy should be carried out and on 03-APR-2025, the patient would have an appointment with the oncologist to check how his progress is and to determine if he would resume Xtandi. Action taken withb Eligard 22.5 mg was Unknown. Dechallenge and rechallenge were Not applicable. Action taken with Eligard 45mg was Dose not changed. Dechallenge and rechallenge were Not applicable.

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

On 06-May-2025, follow-up information was received by Adium via the PSP Solutions (Patient Support Program) (reference number: GT-ADIUM-GT-0902-20231025) from a consumer (non-healthcare professional) and sent to Tolmar on 07-May-2025. New information included: updated concomitant (chemotherapy) details and expiration date of Xtandi (Jun-2026). Added a new co-suspect (Tramadol), treatment medications and lab details. Added new serious (medically significant) events of 'left knee thrombosis' (Thrombosis), unable to walk due to pain in left knee and is on a wheelchair due to it (gait disturbance) and non-serious events of 'left knee pain' (Arthralgia), 'lack of sleep or oversleeping' (sleep disorder), 'tiredness' (Fatigue), 'anxiety' (Anxiety), and 'desperation' (Feeling of despair).

Tramadol was also considered as suspect.

On an unknown date in Dec-2023, the patient was diagnosed with thrombosis in his left knee.

Unknown date, It was reported that the patient had no other discomforts except tiredness and sleep issues, which he tolerated, but he could not tolerate the pain and immobility. In the same duration the patient started taking Tramadol following which he experienced a lot of anxiety, desperation and he almost went crazy. For this reason, the doctor suspended the Tramadol, and he only took it for one week.

The patient had used Xtandi for approximately 6 months without improvement in inflammation or pain, which led to a scintigram that showed no effect, resulting in a switch to chemotherapy. He took Xtandi for 13 months and started with Eligard treatment 3 years ago.

The patient had undergone 5 scintigraphy scans, the last was in Feb-2025, which revealed a large tumor in his left knee, causing severe left knee pain and unable to walk, confining him to a wheelchair. Despite medication, his condition had not improved.

On 03-Apr-2025, during the appointment, the Oncologist decided not to resume Xtandi yet, pending further evaluation of chemotherapy. The patient had been on suspension for approximately 5 months and had received 5 chemotherapies. The next appointment was scheduled for 12-May-2025.

On an unknown date in Aug-2025, the patient was due for his next Eligard injection.

Corrective treatment included dextetoprofen and Toxibo (Unknown) for left knee pain.

Relevant test results included:

On an unknown date in Feb-2025: Radioisotope scan: revealed a large tumor in his left knee (Ref. range: Not provided).

On an unknown date: Radioisotope scan: indicated no effect of Xtandi (Ref. range: Not provided).

On an unknown date: Radioisotope scan: Unknown (Ref. range: Not provided).

On an unknown date: Radioisotope scan: Unknown (Ref. range: Not provided).

Action taken with Eligard 22.5 mg was unknown. De-challenge and rechallenge were not applicable.

Action taken with Eligard 45 mg was dose not changed. De-challenge and rechallenge were not applicable.

The outcome of thrombosis was unknown, arthralgia, sleep disorder, fatigue, gait disturbance was not recovered, and anxiety, feeling of despair was resolved.

The reporter did not assess the seriousness of thrombosis, arthralgia, sleep disorder, fatigue, anxiety, gait disturbance and feeling of despair.

The reporter did not provide the causality of thrombosis, arthralgia, sleep disorder, fatigue, anxiety, gait disturbance and feeling of despair in relationship to Eligard (22.5 mg and 45 mg) and Eligard unspecified device.

No further queries were raised.

Listedness of previously reported events bone metastasis and alopecia was retained as previously assessed.

Thrombosis >Eligard® >unlisted as per CCDS Eligard®> 7-Nov-2024

Thrombosis> Eligard® >unlisted as per Canadian Monograph Eligard®> 2-Apr-2025

Thrombosis> Eligard®>unlisted as per USPI Eligard®>Feb-2025

Thrombosis> Eligard® Unspecified Device>unlisted as per USPI Eligard®>Feb-2025

Continuation Sheet for CIOMS report

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

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

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

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

Fatigue>Eligard® >listed as per CCDS Eligard®> 7-Nov-2024
 Fatigue> Eligard® >listed as per Canadian Monograph Eligard®> 2-Apr-2025
 Fatigue> Eligard®>listed as per USPI Eligard®>Feb-2025
 Fatigue> Eligard® Unspecified Device> listed as per USPI Eligard®>Feb-2025

Arthralgia>Eligard® >listed as per CCDS Eligard®> 7-Nov-2024
 Arthralgia> Eligard® >listed as per Canadian Monograph Eligard®> 2-Apr-2025
 Arthralgia> Eligard®>listed as per USPI Eligard®>Feb-2025
 Arthralgia> Eligard® Unspecified Device> listed as per USPI Eligard®>Feb-2025

Company Remarks (Sender's Comments) :

Evaluator Comment (Tolmar): This 61-year-old male patient had Metastases to bone (prostate cancer metastasis in the bones; one month ago the cancer spread to his bones / prostate cancer metastasized in his bones) and Alopecia (his hair began to fall out (alopecia)) during Eligard (Leuprolide acetate) 22.5 milligram therapy for Prostate cancer. Tolmar assessed the event Metastases to bone as serious (medically significant) based on the clinical relevance and alopecia was assessed non-serious as no jeopardy was reported. Considering that metastases to bone was secondary to natural progression which is inherent to the nature of underlying prostate cancer despite treatment, event was assessed as not related to drug and device component of Eligard. Alopecia was assessed as related with Eligard drug based on temporal relation and known safety profile and not related with device component. Confounders- co-suspect Xtandi and chemotherapies.

FU added events of new serious (medically significant) events of Thrombosis (left knee thrombosis), gait disturbance (unable to walk due to pain in left knee and is on a wheelchair due to it) and non-serious events of Arthralgia (left knee pain), sleep disorder (lack of sleep or oversleeping), Fatigue (tiredness), 'anxiety' (Anxiety), and Feeling of despair (desperation). Tolmar assessed the events thrombosis as serious as it is included in IME list, gait disturbance was considered as serious as per medical judgement as it led to patient to be in a wheelchair and rest of the events as non-serious since they did not meet the ICH seriousness criteria. The causality of event thrombosis was assessed as not related to suspect Eligard(drug and device) considering the nature of the event, etiology, inconsistency with the safety profile of the drug. The causality of events gait disturbance, arthralgia, fatigue, sleep disorder, feeling of despair and anxiety was assessed as not related to suspect Eligard(drug and device) as these could be secondary to thrombosis of knee, metastasis to bone, elderly age and underlying prostate cancer could be confounders for the events.

Additional Information (Continuation...)

Lab Result :

Test Name	Test Date	Test Result	Normal Value
SCINTIGRAPHY	25/Sep/2023		
SCINTIGRAPHY	/Feb/2025		
SCINTIGRAPHY	Unknown		
SCINTIGRAPHY	Unknown		

SCINTIGRAPHY	Unknown		
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Continuation Sheet for CIOMS report

- | | |
|---------------------------|------------------|
| Causality as per reporter | : Not Reported |
| Causality as per Mfr | : Not Related |
| DeChallenge | : Not applicable |
| ReChallenge | : Not Applicable |
- 5) Anxiety (Anxiety - 10002855, Anxiety - 10002855)
- | | |
|---------------------------|------------------|
| Causality as per reporter | : Not Reported |
| Causality as per Mfr | : Not Related |
| DeChallenge | : Not applicable |
| ReChallenge | : Not Applicable |
- 6) desperation (Feeling of despair - 10016344, Feeling of despair - 10016344)
- | | |
|---------------------------|------------------|
| Causality as per reporter | : Not Reported |
| Causality as per Mfr | : Not Related |
| DeChallenge | : Not applicable |
| ReChallenge | : Not Applicable |
- 7) HIS HAIR BEGAN TO FALL OUT (ALOPECIA) (Hair loss - 10019045, Alopecia - 10001760)
- | | |
|---------------------------|------------------|
| Causality as per reporter | : Not Reported |
| Causality as per Mfr | : Related |
| DeChallenge | : Not applicable |
| ReChallenge | : Not Applicable |
- 8) Left knee pain (Arthralgia - 10003239, Arthralgia - 10003239)
- | | |
|---------------------------|------------------|
| Causality as per reporter | : Not Reported |
| Causality as per Mfr | : Not Related |
| DeChallenge | : Not applicable |
| ReChallenge | : Not Applicable |
- 9) Tiredness (Tiredness - 10043890, Fatigue - 10016256)
- | | |
|---------------------------|------------------|
| Causality as per reporter | : Not Reported |
| Causality as per Mfr | : Not Related |
| DeChallenge | : Not applicable |
| ReChallenge | : Not Applicable |

Labeling :

- | | |
|--|-----------|
| 1) Left knee thrombosis | |
| CORE | UnLabeled |
| 2) Unable to walk due to pain in left knee and is on a wheelchair due to it | |
| CORE | UnLabeled |
| 3) PROSTATE CANCER METASTASIS IN THE BONES; ONE MONTH AGO THE CANCER SPREAD TO HIS BONES / PROSTATE CANCER METASTASIZED IN HIS BONES | |
| CORE | Labeled |
| 4) Lack of sleep or oversleeping | |
| CORE | UnLabeled |
| 5) Anxiety | |
| CORE | UnLabeled |
| 6) desperation | |
| CORE | UnLabeled |
| 7) HIS HAIR BEGAN TO FALL OUT (ALOPECIA) | |
| CORE | Labeled |
| 8) Left knee pain | |
| CORE | Labeled |
| 9) Tiredness | |
| CORE | Labeled |
- 2) Drug : Eligard® (Leuprolide acetate)
- | | |
|---------------------------|---|
| Active Substance | : 1) Leuprolide acetate |
| Drug Characterization | : Suspect |
| Form of Admin | : 1) Injection |
| Lot Number | : 1) Unknown |
| Daily Dose | : (45 milligram(s)) |
| Route of Admin | : 1) Subcutaneous |
| Indications | : 1) Prostate cancer [10060862 - Prostate cancer] |
| Action(s) Taken With Drug | : Dose not changed |

Causality

- 1) Left knee thrombosis (Thrombosis - 10043607, Thrombosis - 10043607)
- | | |
|---------------------------|------------------|
| Causality as per reporter | : Not Reported |
| Causality as per Mfr | : Not Related |
| DeChallenge | : Not applicable |
| ReChallenge | : Not Applicable |

Continuation Sheet for CIOMS report

- 2) Unable to walk due to pain in left knee and is on a wheelchair due to it (Walking difficulty - 10047810, Gait disturbance - 10017577)
 Causality as per reporter : Not Reported
 Causality as per Mfr : Not Related
 DeChallenge : Not applicable
 ReChallenge : Not Applicable
- 3) PROSTATE CANCER METASTASIS IN THE BONES; ONE MONTH AGO THE CANCER SPREAD TO HIS BONES / PROSTATE CANCER METASTASIZED IN HIS BONES (Bone metastases - 10005993, Metastases to bone - 10027452)
 Causality as per reporter : Not Reported
 Causality as per Mfr : Not Related
 DeChallenge : Not applicable
 ReChallenge : Not Applicable
- 4) Lack of sleep or oversleeping (Sleep disorder - 10040984, Sleep disorder - 10040984)
 Causality as per reporter : Not Reported
 Causality as per Mfr : Not Related
 DeChallenge : Not applicable
 ReChallenge : Not Applicable
- 5) Anxiety (Anxiety - 10002855, Anxiety - 10002855)
 Causality as per reporter : Not Reported
 Causality as per Mfr : Not Related
 DeChallenge : Not applicable
 ReChallenge : Not Applicable
- 6) desperation (Feeling of despair - 10016344, Feeling of despair - 10016344)
 Causality as per reporter : Not Reported
 Causality as per Mfr : Not Related
 DeChallenge : Not applicable
 ReChallenge : Not Applicable
- 7) HIS HAIR BEGAN TO FALL OUT (ALOPECIA) (Hair loss - 10019045, Alopecia - 10001760)
 Causality as per reporter : Not Reported
 Causality as per Mfr : Related
 DeChallenge : Not applicable
 ReChallenge : Not Applicable
- 8) Left knee pain (Arthralgia - 10003239, Arthralgia - 10003239)
 Causality as per reporter : Not Reported
 Causality as per Mfr : Not Related
 DeChallenge : Not applicable
 ReChallenge : Not Applicable
- 9) Tiredness (Tiredness - 10043890, Fatigue - 10016256)
 Causality as per reporter : Not Reported
 Causality as per Mfr : Not Related
 DeChallenge : Not applicable
 ReChallenge : Not Applicable

Labeling :

- 1) Left knee thrombosis
 CORE UnLabeled
- 2) Unable to walk due to pain in left knee and is on a wheelchair due to it
 CORE
- 3) PROSTATE CANCER METASTASIS IN THE BONES; ONE MONTH AGO THE CANCER SPREAD TO HIS BONES / PROSTATE CANCER METASTASIZED IN HIS BONES
 CORE Labeled
- 4) Lack of sleep or oversleeping
 CORE UnLabeled
- 5) Anxiety
 CORE UnLabeled
- 6) desperation
 CORE UnLabeled
- 7) HIS HAIR BEGAN TO FALL OUT (ALOPECIA)
 CORE Labeled
- 8) Left knee pain
 CORE Labeled
- 9) Tiredness
 CORE Labeled
- 3) Drug : Eligard® Unspecified Device (Leuprolide acetate)
 Active Substance : 1) Leuprolide acetate
 Drug Characterization : Suspect

Continuation Sheet for CIOMS report

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) Left knee thrombosis (Thrombosis - 10043607, Thrombosis - 10043607)
 Causality as per reporter : Not Reported
 Causality as per Mfr : Not Related
 DeChallenge : Not applicable
 ReChallenge : Not Applicable
- 2) Unable to walk due to pain in left knee and is on a wheelchair due to it (Walking difficulty - 10047810, Gait disturbance - 10017577)
 Causality as per reporter : Not Reported
 Causality as per Mfr : Not Related
 DeChallenge : Not applicable
 ReChallenge : Not Applicable
- 3) PROSTATE CANCER METASTASIS IN THE BONES; ONE MONTH AGO THE CANCER SPREAD TO HIS BONES / PROSTATE CANCER METASTASIZED IN HIS BONES (Bone metastases - 10005993, Metastases to bone - 10027452)
 Causality as per reporter : Not Reported
 Causality as per Mfr : Not Related
 DeChallenge : Not applicable
 ReChallenge : Not Applicable
- 4) Lack of sleep or oversleeping (Sleep disorder - 10040984, Sleep disorder - 10040984)
 Causality as per reporter : Not Reported
 Causality as per Mfr : Not Related
 DeChallenge : Not applicable
 ReChallenge : Not Applicable
- 5) Anxiety (Anxiety - 10002855, Anxiety - 10002855)
 Causality as per reporter : Not Reported
 Causality as per Mfr : Not Related
 DeChallenge : Not applicable
 ReChallenge : Not Applicable
- 6) desperation (Feeling of despair - 10016344, Feeling of despair - 10016344)
 Causality as per reporter : Not Reported
 Causality as per Mfr : Not Related
 DeChallenge : Not applicable
 ReChallenge : Not Applicable
- 7) HIS HAIR BEGAN TO FALL OUT (ALOPECIA) (Hair loss - 10019045, Alopecia - 10001760)
 Causality as per reporter : Not Reported
 Causality as per Mfr : Not Related
 DeChallenge : Not applicable
 ReChallenge : Not Applicable
- 8) Left knee pain (Arthralgia - 10003239, Arthralgia - 10003239)
 Causality as per reporter : Not Reported
 Causality as per Mfr : Not Related
 DeChallenge : Not applicable
 ReChallenge : Not Applicable
- 9) Tiredness (Tiredness - 10043890, Fatigue - 10016256)
 Causality as per reporter : Not Reported
 Causality as per Mfr : Not Related
 DeChallenge : Not applicable
 ReChallenge : Not Applicable

Labeling :

- 1) Left knee thrombosis
CORE
- 2) Unable to walk due to pain in left knee and is on a wheelchair due to it
CORE
- 3) PROSTATE CANCER METASTASIS IN THE BONES; ONE MONTH AGO THE CANCER SPREAD TO HIS BONES / PROSTATE CANCER METASTASIZED IN HIS BONES
CORE
- 4) Lack of sleep or oversleeping
CORE
- 5) Anxiety
CORE
- 6) desperation

CORE

CORE

CORE

CORE

Action(s) Taken With Drug : Drug withdrawn

1) Left knee thrombosis (Thrombosis - 10043607, Thrombosis - 10043607)

Causality as per reporter : Not Reported

2) Unable to walk due to pain in left knee and is on a wheelchair due to it (Walking difficulty - 10047810, Gait disturbance - 10017577)

3) PROSTATE CANCER METASTASIS IN THE BONES; ONE MONTH AGO THE CANCER SPREAD TO HIS BONES / PROSTATE CANCER METASTASIZED IN HIS BONES (Bone metastases - 10005993. Metastases to bone - 10027452)

Causality as per reporter : Not Reported

4) Lack of sleep or oversleeping (Sleep disorder - 10040984, Sleep disorder - 10040984)

Causality as per reporter : Not Reported

5) Anxiety (Anxiety - 10002855, Anxiety - 10002855)

Causality as per reporter : Not Reported

6) desperation (Feeling of despair - 10016344, Feeling of despair - 10016344)

Causality as per reporter : Not Reported

7) HIS HAIR BEGAN TO FALL OUT (ALOPECIA) (Hair loss - 10019045, Alopecia - 10001760)

Causality as per reporter : Not Reported

8) Left knee pain (Arthralgia - 10003239, Arthralgia - 10003239)

Causality as per reporter : Not Reported

9) Tiredness (Tiredness - 10043890, Fatigue - 10016256)

Causality as per reporter : Not Reported

5) Drug : OTHER THERAPEUTIC PRODUCTS

Active Substance : 1) treatments for prostate cancer

Drug Characterization : Suspect

Indications : 1) Prostate cancer [10060862 - Prostate cancer]

Action(s) Taken With Drug : Unknown

1) Left knee thrombosis (Thrombosis - 10043607, Thrombosis - 10043607)

Causality as per reporter : Not Reported

2) Unable to walk due to pain in left knee and is on a wheelchair due to it (Walking difficulty - 10047810, Gait disturbance - 10017577)

Causality as per reporter : Not Reported

3) PROSTATE CANCER METASTASIS IN THE BONES; ONE MONTH AGO THE CANCER SPREAD TO HIS BONES / PROSTATE CANCER METASTASIZED IN HIS BONES (Bone metastases - 10005993, Metastases to bone - 10027452)

Causality as per reporter : Not Reported

4) Lack of sleep or oversleeping (Sleep disorder - 10040984, Sleep disorder - 10040984)

Causality as per reporter : Not Reported

5) Anxiety (Anxiety - 10002855, Anxiety - 10002855)

Causality as per reporter : Not Reported

6) desperation (Feeling of despair - 10016344, Feeling of despair - 10016344)

Causality as per reporter : Not Reported

7) HIS HAIR BEGAN TO FALL OUT (ALOPECIA) (Hair loss - 10019045, Alopecia - 10001760)

Causality as per reporter : Not Reported

8) Left knee pain (Arthralgia - 10003239, Arthralgia - 10003239)

Causality as per reporter : Not Reported

9) Tiredness (Tiredness - 10043890, Fatigue - 10016256)

Continuation Sheet for CIOMS report

Causality as per reporter : Not Reported

6) Drug : TRAMADOL
 Active Substance : 1) TRAMADOL
 Drug Characterization : Suspect
 Indications : 1) Product used for unknown indication [10070592 - Product used for unknown indication]
 Action(s) Taken With Drug : Drug withdrawn

Causality

1) Left knee thrombosis (Thrombosis - 10043607, Thrombosis - 10043607)
 Causality as per reporter : Not Reported
 2) Unable to walk due to pain in left knee and is on a wheelchair due to it (Walking difficulty - 10047810, Gait disturbance - 10017577)
 Causality as per reporter : Not Reported
 3) PROSTATE CANCER METASTASIS IN THE BONES; ONE MONTH AGO THE CANCER SPREAD TO HIS BONES / PROSTATE CANCER METASTASIZED IN HIS BONES (Bone metastases - 10005993, Metastases to bone - 10027452)
 Causality as per reporter : Not Reported
 4) Lack of sleep or oversleeping (Sleep disorder - 10040984, Sleep disorder - 10040984)
 Causality as per reporter : Not Reported
 5) Anxiety (Anxiety - 10002855, Anxiety - 10002855)
 Causality as per reporter : Not Reported
 6) desperation (Feeling of despair - 10016344, Feeling of despair - 10016344)
 Causality as per reporter : Not Reported
 7) HIS HAIR BEGAN TO FALL OUT (ALOPECIA) (Hair loss - 10019045, Alopecia - 10001760)
 Causality as per reporter : Not Reported
 8) Left knee pain (Arthralgia - 10003239, Arthralgia - 10003239)
 Causality as per reporter : Not Reported
 9) Tiredness (Tiredness - 10043890, Fatigue - 10016256)
 Causality as per reporter : Not Reported

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

1). Drug : Chemotherapy
 Active Substance : 1) OTHER THERAPEUTIC PRODUCTS
 Form Strength :
 Indications : 1) Prostate cancer [10060862 - Prostate cancer]
 Therapy Dates : 3) From : 03/Mar/2025 To :