

SUSPECT ADVERSE REACTION REPORT												
	PA-TOLMAR, INC.-23PA041383											

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) G-J	1a. COUNTRY PANAMA	2. DATE OF BIRTH			2a. AGE Years 79	3. SEX Male	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day 13	Month Nov	Year 1941			Day 08	Month Mar	Year 2021	
7+13 DESCRIBE REACTION(S) (including relevant tests/lab data)										

1) IN HIS STOMACH IN THE PART OF THE LEFT RIB HE RECEIVED THE BLOW ON THE TIP OF THE TOILET, WHICH WAS A PAIN THAT HE STILL HAD (Rib injury (10057331), Chest injury (10061386))
(25/Feb/2025 -) - Recovering/Resolving

2) DISCOMFORT BECAUSE WHEN HE GRABS AN OBJECT, HE DOES NOT FEEL THAT HE IS HOLDING IT IN HIS HAND (Upper extremities discomfort (10073982), Limb discomfort (10061224))
(/Jun/2023 -) - Unknown

3) FEELS HIS RIGHT HAND ASLEEP/ fingers still go numb. I can move my hand, but when I touch or pick up something, I can't feel anything (Numbness in hand (10049681), Hypoaesthesia (10020937))
(/Jun/2023 -) - Not Recovered/Not Resolved/Ongoing

4) IRRITATION IN BOTH ELBOWS IN THE UPPER PART (Skin irritation (10040880), Skin irritation (10040880))
(06/Jun/2023 -) - Recovered/Resolved

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) 1) Eligard® (Leuprolide acetate, Leuprolide acetate) (Suspect) (Injection)(Unknown)(Unknown)(Unknown)(Unknown) (Unknown)(Unknown)(L2081024AE; Unk; UNK)		20. DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☒ NA 21. DID EVENT REAPPEAR AFTER REINTRODUCTION ☐ YES ☐ NO ☒ NA (NA : Not Applicable)
15. DAILY DOSE(S) 1) (45 milligram(s), in 6 Month) 2) (45 milligram(s), in 6 Month)	16. ROUTE(S) OF ADMINISTRATION 1) Subcutaneous 2) Subcutaneous	
17. INDICATION(S) FOR USE 1) Prostate cancer [10060862 - Prostate cancer]		

Cont..

18. THERAPY DATE(S) (from/to)
1) (26/Mar/2019 - Ongoing)

19. THERAPY DURATION

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction) No concomitants used/reported
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 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. PA-TOLMAR, INC.-23PA041383	
24c. DATE RECEIVED BY MANUFACTURER 30/Jul/2025	24d. REPORT SOURCE ☒ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL	
DATE OF THIS REPORT 08/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) SUFFERED A FALL LEAVING THE BATHROOM/Patient refers that from the fall of 25-Feb-2025 he still does not feel recovered (Fall (10016173), Fall (10016173)(14/Jun/2025 -) - Recovering/Resolving)

6) BECAUSE OF THE FALL HE HURT HIS RIGHT AND LEFT HAND (Hand injury (10079099), Limb injury (10061225)(25/Feb/2025 -) - Not Recovered/Not Resolved/Ongoing)

7) IN HIS STOMACH IN THE PART OF THE LEFT RIB HE RECEIVED THE BLOW ON THE TIP OF THE TOILET, WHICH IS A PAIN THAT HE STILL HAS/ he still has pains that still bother him in the rib (Rib pain (10048722), Musculoskeletal chest pain (10050819)(25/Feb/2025 -) - Not Recovered/Not Resolved/Ongoing)

8) RASH (Rash (10037844), Rash (10037844) - Unknown)

9) Irritation on both upper elbows (skin irritation) like a rash. (Skin irritation (10040880), Skin irritation (10040880) - Not Recovered/Not Resolved/Ongoing)

10) Patient had shoulder pain so he must rest constantly/shoulder pain that is still bothering (Shoulder pain (10040617), Arthralgia (10003239)(25/Feb/2025 -) - Not Recovered/Not Resolved/Ongoing)

11) DIZZINESS (Dizziness (10013573), Dizziness (10013573)(08/Mar/2021 -) - Recovered/Resolved)

12) HOT FLASHES HE FEELS IN BOTH FEET AND IN THE BODY (SENSATION OF HEAT) (Hot flashes (10020407), Hot flush (10060800) - Recovered/Resolved)

13) MALAISE (Malaise (10025482), Malaise (10025482) - Unknown)

14) Hot flashes felt in both feet and throughout the body (Hot flashes (10020407), Hot flush (10060800) - Not Recovered/Not Resolved/Ongoing)

Event Description :

This Study report from PANAMA was received by Adium (reference number: PA-0028-20210319) on 08-JUN-2023 from a Consumer via Patient Support Program "ASOFARMA A TU LADO" regarding an Elderly 79 Years old Male patient who experienced Irritation in both elbows in the upper part (Skin irritation), Dizziness (Dizziness), during Eligard (Leuprolide acetate) 45 milligram therapy for Prostate cancer. The needle component of the constituent device was not identified in the report, XTANDI was also considered as suspect. The report was sent to Tolmar on 08-JUN-2023.

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

Concomitant medications were not reported.

On 26-MAR-2019, 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 08-MAR-2021, after four doses of Eligard, the patient experienced Dizziness. On an unspecified date in APR-2023, the patient received Eligard 45 milligram, q 6 month via Subcutaneous use (Lot numbers and Expiration dates were not provided). On 06-JUN-2023, the patient started with irritation in both elbows in the upper part (skin irritation) as if it were a rash. On 08-JUN-2023, the patient will go to the doctor for a consultation and to be prescribed some medication. The patient did not currently use any medication for this symptom. The patient two weeks ago (start date unknown) had the same irritation mentioned above, but the patient was applied a cocoa cream and disappeared. No further details were provided. 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 Skin irritation was Not Recovered/Not Resolved. The outcome of Dizziness was Unknown.

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

On 19-JUN-2023, follow-up information was received by Adium via Patient Support Program "ASOFARMA A TU LADO" (reference number: PA-0028-20210319) from the Consumer and sent to Tolmar on 20-JUN-2023. Added events of "rash" (Rash) and "Hot flashes he feels in both feet and in the body (sensation of heat)" (Hot flashes). Updated outcome of Skin irritation.

It was referred that Irritation in both elbows (that started on 06 Jun 2023) in the upper part was not related to the Xtandi medication, that probably these symptoms were due to the heat, because the day after the adverse event was reported he no longer had irritation. The irritation on both elbows in the upper part (skin irritation) was not similar to some kind of eruption, which was like a rash (unknown onset date). Moreover, on an unknown date, the patient experienced some hot flashes, he felt in both feet and in the body (sensation of heat). The physician commented to the patient that it was due to the side effects of the Xtandi medication, that it was normal to feel these symptoms and that it would soon pass. 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 Skin irritation was Recovered/Resolved. The outcome of Hot flashes was Not Recovered/Not Resolved. The outcome of Rash was Unknown.

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

Continuation Sheet for CIOMS report

On 29-JUN-2023, follow-up information was received by Adium (reference number: PA-0028-20210319) from the Consumer and sent to Tolmar on 30-JUN-2023. Added events of "feels his right hand asleep" (Numbness in hand), "malaise" (malaise) and "discomfort because when he grabs an object, he does not feel that he is holding it in his hand" (upper extremities discomfort). Updated outcome and reporter causality of hot flashes.

Reportedly, the final result of the adverse event sensation of heat (that had started on an unknown onset date) was recovered and the patient referred that it was related to the medication. Moreover, it was referred that 4 to 5 days ago (Jun 2023), he did not remember the date, he felt his right hand asleep (numbness in hand), it did not cause his malaise (malaise start date was unknown), but it caused his discomfort because when he grabbed an object, he did not feel that he was holding it in his hand (Jun 2023). 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 Upper extremities discomfort was Unknown. The outcome of Numbness in hand was Unknown. The outcome of Hot flashes was Recovered/Resolved. The outcome of Malaise was Unknown.

The reporter did not assess the seriousness of Upper extremities discomfort and assessed the causality in relationship to Eligard as Not Reported. The reporter did not assess the seriousness of Numbness in hand and assessed the causality in relationship to Eligard as Not Reported. The reporter did not assess the seriousness of Hot flashes and assessed the causality in relationship to Eligard as Related. The reporter did not assess the seriousness of Malaise and assessed the causality in relationship to Eligard as Not Reported.

On 12-JUL-2023, follow-up information was received by Adium (reference number: PA-0028-20210319) from a Consumer and sent to Tolmar on 13-JUL-2023. New information included: no contact information.

Reportedly, a patient's relative did not accept the call and indicated that it be called at another time when the patient was there. Did not provide more information.

Since no new information was provided. This follow up was considered non-significant.

On 31-JUL-2023, follow-up information was received by Adium (reference number: PA-0028-20210319) from a Consumer (patient's relative) and sent to Tolmar on 31-JUL-2023. Added consumer as reporter. Query attempt was completed. The patient's relative did not accept the call and declined to give information.

Since no new information was provided, this follow up was considered non-significant.

On 27-FEB-2025, follow-up information was received by Adium via Patient Support Program (reference number: PA-0028-20210319) from a Consumer/ Other Non-Health Prof and sent to Tolmar on 28-FEB-2025. New information included: added medically significant event of "in his stomach in the part of the left rib he received the blow on the tip of the toilet, which was a pain that he still had" (Rib injury), added new non-serious events of "suffered a fall leaving the bathroom" (Fall), "because of the fall he hurt his right and left hand" (Hand injury), treatment medication, laboratory tests.

On 25-FEB-2025, unknown time after most recent dose of Eligard, the patient suffered a fall when leaving the bathroom as he left the bathroom, he grabbed a lever or curtain rods (it was unknown what exactly he was referring to), and the carpet moved causing him to fall. The patient was conscious, and because of the fall he hurt his right and left hand, since the patient placed both hands in front of him so that his head would not hit the toilet. Further the patient reported that in his stomach in the part of the left rib he received the blow on the tip of the toilet, which caused pain that he still had. Due to this reason, he was not able to go out to the street to request his next box of Xtandi. On the same day, the patient went to the emergency hospital where he had an x-ray, which revealed that there was no fracture, but he did have pain. Corrective treatment was reported as Contractil plus (diclofenac potassium, thiocolchicoside) for rib pain. Action taken with Eligard in response to the events was Dose Not Changed. De-challenge and re-challenge were not applicable. The outcome of Fall was Not Recovered/Not Resolved. The outcome of Rib injury was Not Recovered/Not Resolved. The outcome of Hand injury was Not Recovered/Not Resolved. The outcome of Rib pain was Not Recovered/Not Resolved.

Relevant test results included:

25-FEB-2025: X-ray: revealed no fracture (Ref range: Not provided).

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

On 05-MAR-2025, upon internal review, case upgraded to serious due to medically significant event of "in his stomach in the part of the left rib he received the blow on the tip of the toilet, which was a pain that he still had (Rib injury)" and corrected narrative of version from 27-FEB-2025. No further changes were performed.

On 19-May-2025, follow up information was received via by Adium via Patient Support Program "ASOFARMA A TU LADO ((reference number: (PA-0028-20210319), from a consumer. New information included: Verbatim updated from 'Suffered a fall leaving the bathroom' to 'suffered a fall leaving the bathroom/Patient refers that from the fall of 25-Feb-2025 he still does not feel recovered' (fall) and 'in his stomach in the part of the left rib he received the blow on the tip of the toilet, which is a pain that he still has' to 'in his stomach in the part of the left rib he received the blow on the tip of the toilet, which is a pain that he still has/ he still has pains that still bother him in the rib' (musculoskeletal chest pain). Added a non-serious event 'patient had shoulder pain so he must rest constantly' (arthralgia) was added. Narrative was updated.

On 25-Feb-2025, the patient falls, and he still does not feel recovered because he still had pain which bother his rib and shoulder and he must take rest constantly, but he mentioned he walked and performed his all activities. He mentioned that he manged not to hit his face.

Corrective treatment was unknown.

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

Continuation Sheet for CIOMS report

The outcome of fall, musculoskeletal chest pain and arthralgia was not recovered.

The reporter did not assess the seriousness of events fall and musculoskeletal chest pain.

The reporter did not assess the seriousness of event arthralgia.

The reporter did not provide the causality of fall, musculoskeletal chest pain and arthralgia in relationship to Eligard and Eligard Unspecified Device.

No further query was raised.

On 16-Jul-2025, the follow-up information was received via by Adium via Patient Support Program "ASOFARMA A TU LADO ((reference number: PA-0028-20210319 (8)), from a consumer. The report was sent to Tolmar on 17-Jul-2025. New information included: New non-serious event of "Hot flashes felt in both feet and throughout the body" (hot flush), "irritation on both upper elbows (skin irritation) like a rash" (Skin irritation). Clinical details for event dizziness, arthralgia and hypoaesthesia was updated. The outcome of event dizziness was updated from 'unknown' to 'recovered' and the outcome of event hypoaesthesia was updated from 'unknown' to 'not recovered'. The verbatim of event (Hypoaesthesia) was updated from "feels his right hand asleep" to "feels his right hand asleep/ fingers still go numb. I can move my hand, but when I touch or pick up something, I can't feel anything". The verbatim of event arthralgia was updated from "Patient had shoulder pain so he must rest constantly" to "Patient had shoulder pain so he must rest constantly/shoulder pain that is still bothering" The details for co-suspect Xtandi were updated.

On an unknown date, the patient had hot flashes felt in both feet and throughout the body and had irritation on both upper elbows (skin irritation) like a rash. No further details were provided.

On 14-May-2025, the patient fall symptoms still hurts not every day, but it comes and go, and his shoulder pain was still bothering. No further details were provided.

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

The outcome of hypoaesthesia, arthralgia, fall, hot flush and skin irritation was not recovered.

The outcome of dizziness was recovered.

The reporter did not assess the seriousness of dizziness, hypoaesthesia, arthralgia, hot flush and skin irritation.

The reporter did not provide the causality of dizziness, hypoaesthesia, arthralgia, hot flush and skin irritation in relationship to Eligard and Eligard Unspecified Device.

No further query was raised.

Listedness of previously reported events were retained as previously assessed.

New event listedness

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

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

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

On 30-Jul-2025, the follow-up information was received by Adium via ASOFARMA A TU LADO Patient Support Program (reference number: PA-0028-20210319 (9)), from a consumer and sent to Tolmar on 31-Jul-2025. New information included: added a medical history of "Osteoarthritis" and Eligard dose details. Updated outcome of "chest injury" and "fall" from "not recovered" to "recovering". All responses to the query were added, and the narrative was updated.

The patient's medical history included osteoarthritis.

The patient reported wear and tear in the right knee, which began 15 years ago when they experienced pain while getting out of a car. A doctor administered an injection and advised against a second dose due to cancer risk. The knee remained problem-free until the recent fall, when the patient

Continuation Sheet for CIOMS report

stood firmly on that leg. The outcome of this knee issue remained unknown, as the patient received mixed messages from doctors. They were told that if the knee did not bother them, no action was necessary, and surgery was discouraged due to age-related healing concerns.

It was confirmed that the patient continued taking Enzalutamide and had not stopped its use.

Regarding Eligard, the patient reported receiving the medication approximately a month to a month and a half ago. They were awaiting a consultation with their doctor to determine when to reapply. Although the appointment was scheduled for today, the patient did not expect to attend due to rain.

On 19-Jun-2025, the patient received Eligard 45 mg of every 6 months via subcutaneous use for prostate cancer (lot numbers: L2081024AE; Unk; Unk and expiration dates: Feb-2026; Unk; Unk).

On 14-Jul-2025, a fall was experienced, rather than the previously suggested dates of 14-May and 25-Feb and its was confirmed by the patient. No further falls were reported after that incident.

Although the patient previously stated they had never experienced dizziness, they later described a rare and unexplained episode. While exiting the bathroom, the patient grabbed the top part of the shower curtain, placed their right foot on the floor, and lifted the other foot to step out. At that moment, they felt as though they were going to fall and subsequently did. The patient hit the toilet, used their hand to protect their face, and impacted their left rib. Initially, they did not feel pain in the rib area but later reported discomfort. Tests revealed no fractures. The medical center attributed the pain to the impact and the patient's age. The patient described the sensation as if someone had hit them with a stick, though not severely enough to suggest a break. The pain began around 22-Jun-2025, and varied day to day. The doctor prescribed a painkiller and diagnosed inflammation. The patient remained uncertain about the diagnosis but indicated they were in recovery.

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

The outcome of chest injury and fall was recovering.

The reporters did not assess the seriousness of chest injury and fall.

The reporter did not provide the causality of chest injury and fall in relationship to Eligard and Eligard unspecified device.

No further queries were raised.

Company Remarks (Sender's Comments) :

Evaluator Comment (Tolmar): An elderly male patient had Chest injury (in his stomach in the part of the left rib he received the blow on the tip of the toilet, which was a pain that he still had), Fall (suffered a fall leaving the bathroom), Limb injury (because of the fall he hurt his right and left hand), Musculoskeletal chest pain (in his stomach in the part of the left rib he received the blow on the tip of the toilet, which is a pain that he still has), Skin irritation (Irritation in both elbows in the upper part), Limb discomfort (discomfort because when he grabs an object, he does not feel that he is holding it in his hand), Rash (Rash), Hypoaesthesia (feels his right hand asleep/ fingers still go numb. I can move my hand, but when I touch or pick up something, I can't feel anything), Hot flush (Hot flashes he feels in both feet and in the body (sensation of heat)), Dizziness (Dizziness) and Malaise (malaise) during Eligard (Leuprolide acetate) 45 milligram therapy for Prostate cancer. Tolmar assessed Chest injury as medically significant based on their nature and potential patient jeopardy and the remaining events as non-serious since there was no immediate jeopardy to patient and they did not meet ICH seriousness criteria. Dizziness, Hot flush and Malaise were assessed as related to Eligard drug (unrelated to device) based on temporal relation and known safety profile of the drug. Confounder- Xtandi. Other events were assessed as not related to Eligard (drug and device) based on the etio-pathology of the event, known safety profile of the drug and inconsistency with drug properties. Chest injury, Limb injury and Musculoskeletal chest pain were result of fall which was likely accidental based on the reported sequence of events in the case. Limb discomfort could be in association with Hypoaesthesia. Risk factor- elderly age. Rash was reportedly in relation to Xtandi.

FU added event of arthralgia (Patient had shoulder pain so he must rest constantly/shoulder pain that is still bothering). Tolmar assessed the reported event as non-serious since it did not meet the ICH seriousness criteria. The causality of event arthralgia was assessed as not related as it occurred due to fall and elderly age could be a risk factor for the event.

FU-Events hot flush (Hot flashes felt in both feet and throughout the body) and skin irritation (Irritation on both upper elbows (skin irritation) like a rash) were added. Tolmar assessed the reported event as non-serious since it did not meet the ICH seriousness criteria. The causality of event Hot flush was assessed as related to Eligard drug (unrelated to device) based on temporal relation and known safety profile of the drug. The event skin irritation was assessed as not related to Eligard (drug and device) based on the etio-pathology of the event, known safety profile of the drug and inconsistency with drug properties. Causality of previously reported events were retained as previously assessed.

Additional Information (Continuation...)

Lab Result :

Test Name	Test Date	Test Result	Normal Value
X-RAY	25/Feb/2025		

Continuation Sheet for CIOMS report

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

1) Test Name: X-RAY

Result Unstructured Data (free text) : no fracture

Test Date: 25/Feb/2025

Lab Comments :

1) Test Name : X-RAY

Lab Comments : no fracture

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
	4) Injection
	5) Injection
	6) Injection
	7) Injection
Lot Number	: 1) Unknown
	2) Unknown
	3) Unknown
	4) Unknown
	5) Unknown
	6) Unknown
	7) L2081024AE; Unk; UNK
Daily Dose	: (45 milligram(s), in 6 Month)
	(45 milligram(s), in 6 Month)
	(45 milligram(s), in 6 Month)
	(45 milligram(s), in 6 Month)
	(45 milligram(s), in 6 Month)
	(45 milligram(s), in 6 Month)
	(45 milligram(s), in 6 Month)
Route of Admin	: 1) Subcutaneous
	2) Subcutaneous
	3) Subcutaneous
	4) Subcutaneous
	5) Subcutaneous
	6) Subcutaneous
	7) Subcutaneous
Indications	: 1) Prostate cancer [10060862 - Prostate cancer]
Therapy Dates	: 1) From : 26/Mar/2019 To :Continuing
	6) From : /Apr/2023 To :Continuing
	7) From : 19/Jun/2025 To :Continuing
Action(s) Taken With Drug	: Dose not changed

Causality

1) IN HIS STOMACH IN THE PART OF THE LEFT RIB HE RECEIVED THE BLOW ON THE TIP OF THE TOILET, WHICH WAS A PAIN THAT HE STILL HAD (Rib injury - 10057331, Chest injury - 10061386)

Causality as per reporter : Not Reported

Causality as per Mfr : Not Related

DeChallenge : Not applicable

ReChallenge : Not Applicable

2) DISCOMFORT BECAUSE WHEN HE GRABS AN OBJECT, HE DOES NOT FEEL THAT HE IS HOLDING IT IN HIS HAND (Upper extremities discomfort - 10073982, Limb discomfort - 10061224)

Causality as per reporter : Not Reported

Causality as per Mfr : Not Related

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- DeChallenge : Not applicable
ReChallenge : Not Applicable
- 3) FEELS HIS RIGHT HAND ASLEEP/ fingers still go numb. I can move my hand, but when I touch or pick up something, I can't feel anything (Numbness in hand - 10049681, Hypoaesthesia - 10020937)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
- 4) IRRITATION IN BOTH ELBOWS IN THE UPPER PART (Skin irritation - 10040880, Skin irritation - 10040880)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
- 5) SUFFERED A FALL LEAVING THE BATHROOM/Patient refers that from the fall of 25-Feb-2025 he still does not feel recovered (Fall - 10016173, Fall - 10016173)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
- 6) BECAUSE OF THE FALL HE HURT HIS RIGHT AND LEFT HAND (Hand injury - 10079099, Limb injury - 10061225)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
- 7) IN HIS STOMACH IN THE PART OF THE LEFT RIB HE RECEIVED THE BLOW ON THE TIP OF THE TOILET, WHICH IS A PAIN THAT HE STILL HAS/ he still has pains that still bother him in the rib (Rib pain - 10048722, Musculoskeletal chest pain - 10050819)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
- 8) RASH (Rash - 10037844, Rash - 10037844)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
- 9) Irritation on both upper elbows (skin irritation) like a rash. (Skin irritation - 10040880, Skin irritation - 10040880)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
- 10) Patient had shoulder pain so he must rest constantly/shoulder pain that is still bothering (Shoulder pain - 10040617, Arthralgia - 10003239)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
- 11) DIZZINESS (Dizziness - 10013573, Dizziness - 10013573)
Causality as per reporter : Not Reported
Causality as per Mfr : Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
- 12) HOT FLASHES HE FEELS IN BOTH FEET AND IN THE BODY (SENSATION 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
- 13) MALAISE (Malaise - 10025482, Malaise - 10025482)
Causality as per reporter : Not Reported
Causality as per Mfr : Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
- 14) Hot flashes felt in both feet and throughout the body (Hot flashes - 10020407, Hot flush - 10060800)
Causality as per reporter : Not Reported
Causality as per Mfr : Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Continuation Sheet for CIOMS report

Labeling :

- 1) IN HIS STOMACH IN THE PART OF THE LEFT RIB HE RECEIVED THE BLOW ON THE TIP OF THE TOILET, WHICH WAS A PAIN THAT HE STILL HAD
CORE UnLabeled
 - 2) DISCOMFORT BECAUSE WHEN HE GRABS AN OBJECT, HE DOES NOT FEEL THAT HE IS HOLDING IT IN HIS HAND
CORE UnLabeled
 - 3) FEELS HIS RIGHT HAND ASLEEP/ fingers still go numb. I can move my hand, but when I touch or pick up something, I can't feel anything
CORE Labeled
 - 4) IRRITATION IN BOTH ELBOWS IN THE UPPER PART
CORE UnLabeled
 - 5) SUFFERED A FALL LEAVING THE BATHROOM/Patient refers that from the fall of 25-Feb-2025 he still does not feel recovered
CORE UnLabeled
 - 6) BECAUSE OF THE FALL HE HURT HIS RIGHT AND LEFT HAND
CORE UnLabeled
 - 7) IN HIS STOMACH IN THE PART OF THE LEFT RIB HE RECEIVED THE BLOW ON THE TIP OF THE TOILET, WHICH IS A PAIN THAT HE STILL HAS/ he still has pains that still bother him in the rib
CORE UnLabeled
 - 8) RASH
CORE UnLabeled
 - 9) Irritation on both upper elbows (skin irritation) like a rash.
CORE UnLabeled
 - 10) Patient had shoulder pain so he must rest constantly/shoulder pain that is still bothering
CORE Labeled
 - 11) DIZZINESS
CORE Labeled
 - 12) HOT FLASHES HE FEELS IN BOTH FEET AND IN THE BODY (SENSATION OF HEAT)
CORE Labeled
 - 13) MALAISE
CORE Labeled
 - 14) Hot flashes felt in both feet and throughout the body
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) IN HIS STOMACH IN THE PART OF THE LEFT RIB HE RECEIVED THE BLOW ON THE TIP OF THE TOILET, WHICH WAS A PAIN THAT HE STILL HAD (Rib injury - 10057331, Chest injury - 10061386)
 Causality as per reporter : Not Reported
 Causality as per Mfr : Not Related
 DeChallenge : Not applicable
 ReChallenge : Not Applicable
- 2) DISCOMFORT BECAUSE WHEN HE GRABS AN OBJECT, HE DOES NOT FEEL THAT HE IS HOLDING IT IN HIS HAND (Upper extremities discomfort - 10073982, Limb discomfort - 10061224)
 Causality as per reporter : Not Reported
 Causality as per Mfr : Not Related
 DeChallenge : Not applicable
 ReChallenge : Not Applicable
- 3) FEELS HIS RIGHT HAND ASLEEP/ fingers still go numb. I can move my hand, but when I touch or pick up something, I can't feel anything (Numbness in hand - 10049681, Hypoaesthesia - 10020937)
 Causality as per reporter : Not Reported
 Causality as per Mfr : Not Related
 DeChallenge : Not applicable
 ReChallenge : Not Applicable
- 4) IRRITATION IN BOTH ELBOWS IN THE UPPER PART (Skin irritation - 10040880, Skin irritation - 10040880)
 Causality as per reporter : Not Reported
 Causality as per Mfr : Not Related
 DeChallenge : Not applicable
 ReChallenge : Not Applicable
- 5) SUFFERED A FALL LEAVING THE BATHROOM/Patient refers that from the fall of 25-Feb-2025 he still does not feel recovered (Fall - 10016173, Fall - 10016173)

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- Causality as per reporter : Not Reported
 Causality as per Mfr : Not Related
 DeChallenge : Not applicable
 ReChallenge : Not Applicable
- 6) BECAUSE OF THE FALL HE HURT HIS RIGHT AND LEFT HAND (Hand injury - 10079099, Limb injury - 10061225)
 Causality as per reporter : Not Reported
 Causality as per Mfr : Not Related
 DeChallenge : Not applicable
 ReChallenge : Not Applicable
- 7) IN HIS STOMACH IN THE PART OF THE LEFT RIB HE RECEIVED THE BLOW ON THE TIP OF THE TOILET, WHICH IS A PAIN THAT HE STILL HAS/ he still has pains that still bother him in the rib (Rib pain - 10048722, Musculoskeletal chest pain - 10050819)
 Causality as per reporter : Not Reported
 Causality as per Mfr : Not Related
 DeChallenge : Not applicable
 ReChallenge : Not Applicable
- 8) RASH (Rash - 10037844, Rash - 10037844)
 Causality as per reporter : Not Reported
 Causality as per Mfr : Not Related
 DeChallenge : Not applicable
 ReChallenge : Not Applicable
- 9) Irritation on both upper elbows (skin irritation) like a rash. (Skin irritation - 10040880, Skin irritation - 10040880)
 Causality as per reporter : Not Reported
 Causality as per Mfr : Not Related
 DeChallenge : Not applicable
 ReChallenge : Not Applicable
- 10) Patient had shoulder pain so he must rest constantly/shoulder pain that is still bothering (Shoulder pain - 10040617, Arthralgia - 10003239)
 Causality as per reporter : Not Reported
 Causality as per Mfr : Not Related
 DeChallenge : Not applicable
 ReChallenge : Not Applicable
- 11) DIZZINESS (Dizziness - 10013573, Dizziness - 10013573)
 Causality as per reporter : Not Reported
 Causality as per Mfr : Not Related
 DeChallenge : Not applicable
 ReChallenge : Not Applicable
- 12) HOT FLASHES HE FEELS IN BOTH FEET AND IN THE BODY (SENSATION 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
- 13) MALAISE (Malaise - 10025482, Malaise - 10025482)
 Causality as per reporter : Not Reported
 Causality as per Mfr : Not Related
 DeChallenge : Not applicable
 ReChallenge : Not Applicable
- 14) Hot flashes felt in both feet and throughout the body (Hot flashes - 10020407, Hot flush - 10060800)
 Causality as per reporter : Not Reported
 Causality as per Mfr : Not Related
 DeChallenge : Not applicable
 ReChallenge : Not Applicable

Labeling :

- 1) IN HIS STOMACH IN THE PART OF THE LEFT RIB HE RECEIVED THE BLOW ON THE TIP OF THE TOILET, WHICH WAS A PAIN THAT HE STILL HAD
 CORE
- 2) DISCOMFORT BECAUSE WHEN HE GRABS AN OBJECT, HE DOES NOT FEEL THAT HE IS HOLDING IT IN HIS HAND
 CORE
- 3) FEELS HIS RIGHT HAND ASLEEP/ fingers still go numb. I can move my hand, but when I touch or pick up something, I can't feel anything
 CORE
- 4) IRRITATION IN BOTH ELBOWS IN THE UPPER PART
 CORE
- 5) SUFFERED A FALL LEAVING THE BATHROOM/Patient refers that from the fall of 25-Feb-2025 he still does not feel recovered
 CORE
- 6) BECAUSE OF THE FALL HE HURT HIS RIGHT AND LEFT HAND
 CORE

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7) IN HIS STOMACH IN THE PART OF THE LEFT RIB HE RECEIVED THE BLOW ON THE TIP OF THE TOILET, WHICH IS A PAIN THAT HE STILL HAS/ he still has pains that still bother him in the rib

CORE

8) RASH

CORE

9) Irritation on both upper elbows (skin irritation) like a rash.

CORE

10) Patient had shoulder pain so he must rest constantly/shoulder pain that is still bothering

CORE

11) DIZZINESS

CORE

12) HOT FLASHES HE FEELS IN BOTH FEET AND IN THE BODY (SENSATION OF HEAT)

CORE

13) MALAISE

CORE

14) Hot flashes felt in both feet and throughout the body

CORE

3) Drug	: XTANDI
Active Substance	: 1) ENZALUTAMIDE
Drug Characterization	: Suspect
Form of Admin	: 1) Capsule
	2) Capsule
Lot Number	: 1) L1939652AAC; Unk; Unk
	2) Unknown
Daily Dose	: (40 milligram(s), 1 in 1 Day)
	(40 milligram(s), 1 in 1 Day)
Indications	: 1) Prostate cancer [10060862 - Prostate cancer]
Therapy Dates	: 1) From : 15/Feb/2021 To : Continuing
	2) From : 28/Feb/2022 To : Continuing
Action(s) Taken With Drug	: Dose not changed

Causality

1) IN HIS STOMACH IN THE PART OF THE LEFT RIB HE RECEIVED THE BLOW ON THE TIP OF THE TOILET, WHICH WAS A PAIN THAT HE STILL HAD (Rib injury - 10057331, Chest injury - 10061386)

Causality as per reporter : Not Reported

2) DISCOMFORT BECAUSE WHEN HE GRABS AN OBJECT, HE DOES NOT FEEL THAT HE IS HOLDING IT IN HIS HAND (Upper extremities discomfort - 10073982, Limb discomfort - 10061224)

Causality as per reporter : Not Reported

3) FEELS HIS RIGHT HAND ASLEEP/ fingers still go numb. I can move my hand, but when I touch or pick up something, I can't feel anything (Numbness in hand - 10049681, Hypoaesthesia - 10020937)

Causality as per reporter : Not Reported

4) IRRITATION IN BOTH ELBOWS IN THE UPPER PART (Skin irritation - 10040880, Skin irritation - 10040880)

Causality as per reporter : Not Reported

5) SUFFERED A FALL LEAVING THE BATHROOM/Patient refers that from the fall of 25-Feb-2025 he still does not feel recovered (Fall - 10016173, Fall - 10016173)

Causality as per reporter : Not Reported

6) BECAUSE OF THE FALL HE HURT HIS RIGHT AND LEFT HAND (Hand injury - 10079099, Limb injury - 10061225)

Causality as per reporter : Not Reported

7) IN HIS STOMACH IN THE PART OF THE LEFT RIB HE RECEIVED THE BLOW ON THE TIP OF THE TOILET, WHICH IS A PAIN THAT HE STILL HAS/ he still has pains that still bother him in the rib (Rib pain - 10048722, Musculoskeletal chest pain - 10050819)

Causality as per reporter : Not Reported

8) RASH (Rash - 10037844, Rash - 10037844)

Causality as per reporter : Not Reported

9) Irritation on both upper elbows (skin irritation) like a rash. (Skin irritation - 10040880, Skin irritation - 10040880)

Causality as per reporter : Not Reported

10) Patient had shoulder pain so he must rest constantly/shoulder pain that is still bothering (Shoulder pain - 10040617, Arthralgia - 10003239)

Causality as per reporter : Not Reported

11) DIZZINESS (Dizziness - 10013573, Dizziness - 10013573)

Causality as per reporter : Not Reported

12) HOT FLASHES HE FEELS IN BOTH FEET AND IN THE BODY (SENSATION OF HEAT) (Hot flashes - 10020407, Hot flush - 10060800)

Causality as per reporter : Not Reported

13) MALAISE (Malaise - 10025482, Malaise - 10025482)

Causality as per reporter : Not Reported

14) Hot flashes felt in both feet and throughout the body (Hot flashes - 10020407, Hot flush - 10060800)

Causality as per reporter : Not Reported

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
- 4) 45 milligram, q 6 month
- 5) 45 milligram, q 6 month
- 6) 45 milligram, q 6 month
- 7) 45 milligram, q 6 month

23. OTHER RELEVANT HISTORY (Continuation...)

- 2) WEAR AND TEAR IN THE RIGHT KNEE (10023476 , Knee osteoarthritis)