SUSPECT ADVERSE REACTION REPORT

PA-Tolmar-TLM-2025-00366

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE Years	3. SEX	4-6 REACTION ONSET		
		Day	Month	Year			Day	Month	Year
FLS	PANAMA	01	Aug	1933	91	Male		Nov	2023

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

1) FALL (Fall (10016173), Fall (10016173))
(07/Oct/2024 -) - Unknown
2) HIP FRACTURE (Hip fracture (10020100), Hip fracture (10020100))
(07/Oct/2024 -) - Unknown
3) RIGHT WRIST FRACTURE (Wrist fracture (10048049), Wrist fracture (10048049))
(07/Oct/2024 -) - Unknown
4) FOOT SWELLING AND UGLY THINGS CAME OUT AS IF IT WAS A ROTTEN FOOT (Swelling of feet (10042693), Peripheral swelling (10048959))
(/Nov/2023 -) - Unknown

Cont..

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☑ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENCE OR SIGNIFICANT DISABILITY/INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II. SUSPECT DRUG(S)INFORMATION

14. SUSPECT DRUG(S)(include generic name)

1) Eligard® (Leuprolide acetate, Leuprolide acetate) (Suspect) (45 Milligram, Injection)(Unknown)(45 Milligram, Injection)

Cont..

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

15. DAILY DOSE(S)

1) (45 milligram(s), 1 in 6 Month)

2) (45 milligram(s), 1 in 6 Month)

Cont..

16. ROUTE(S) OF ADMINISTRATION

1) Subcutaneous
2) Subcutaneous

Cont..

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

(NA : Not Applicable)

17. INDICATION(S) FOR USE

1) Prostate cancer [10060862 - Prostate cancer]

Cont..

18. THERAPY DATE(S) (from/to)	19. THERAPY DURATION
1) (14/Jun/2021 - /Jun/2025)	1) 1449 Days

III. CONCOMITANT DRUG(S) AND HISTORY

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

1)CEFALMIN CEFRADINE

Cont..

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

1) PROSTATE CANCER (10060862, Prostate cancer) (//2005 -) (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	24b. MFR CONTROL NO.
☐ YES ☐ NO	PA-Tolmar-TLM-2025-00366
24c. DATE RECEIVED BY MANUFACTURER	24d. REPORT SOURCE
15/Aug/2025	☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT	25a. REPORT TYPE
20/Aug/2025	☐ INITIAL ☑ FOLLOWUP

= Continuation attached sheet(s)..

Continuation Sheet for CIOMS report

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

5) ULCERS ON BUTTOCK (Amebic skin ulceration (10001925), Amoebic skin ulcer (10001992)(//2024 -) - Unknown)

6) EAR PAIN (Ear pain (10014020), Ear pain (10014020)(02/Apr/2025 -) - Not Recovered/Not Resolved/Ongoing)

7) ELEVATED BLOOD NEUTROPHILS (Neutrophil count increased (10029368), Neutrophil count increased (10029368) - Unknown)

8) Interruption of Eligard (Therapy interrupted (10066377), Therapy interrupted (10066377)(/Jun/2025 -) - Unknown)

9) HIGH EOSINOPHILS (Eosinophil count high (10014944), Eosinophil count increased (10014945) - Unknown)

10) LOW HAEMOGLOBIN (Haemoglobin decreased (10018884), Haemoglobin decreased (10018884) - Unknown)

11) ERYTHROCYTE COUNT 4.42 (10^3 ML) (RBC decreased (10037926), Red blood cell count decreased (10038153) - Unknown)

12) FEELING DIZZY (Dizziness (10013573), Dizziness (10013573)(01/Aug/2024 -) - Not Recovered/Not Resolved/Ongoing)

Event Description :

This Study report from PANAMA was received by Adium (reference number: PA-ADIUM-PA-0045-20240802) on 02-AUG-2024 from a Consumer/ Other Non-Health Prof regarding an Elderly 91-Years-old Male patient who experienced feeling dizzy (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 03-AUG-2024.

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

Concomitant medications were not reported.

On 14-JUN-2022, the patient began receiving Eligard 45 milligram, q 6 month via Subcutaneous use for Prostate cancer (Lot numbers and expiration date were not reported).

On 01-AUG-2024, time to onset unknown, after the most recent dose of Eligard, the patient was feeling dizzy. 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 dizziness was not recovered/not resolved.

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

On 08-NOV-2024, follow-up information was received by Adium (reference number: PA-ADIUM-PA-0045-20240802) from a Consumer/Other Non-Health Prof and sent to Tolmar on 11-NOV-2024. New information included the Latest Eligard dose, Concomitant medications, lab data, medical history and procedures was reported. new serious (Hospitalization) events Fall (Fall), Hip fracture (Hip fracture), Right wrist fracture (Wrist fracture). Non-Serious events ulcers on buttock (Ulcer), and Foot swelling and ugly things came out as if it was a rotten foot (Foot swelling)

The patient's medical history and current conditions included Prostate cancer, Blood pressure increased, Wheelchair user, Prosthesis user, walking aid user, Cast application, CALUTOL.

Concomitant medications included CEFALMIN [CEFRADINE], ENALAPRIL, NORBAX (adolipin), ATORVASTATIN.

On an unspecified date of NOV-2023, unknown after the most recent dose of Eligard, the patient experienced Foot swelling and ugly things came out as if it was a rotten foot. On an unspecified date of AUG-2024, the patient received his latest dose of Eligard 45 milligram, q 6 month via Subcutaneous use for Prostate Cancer (Lot number and expiration date details were not provided). On 07-OCT-2024, unknown after the most recent dose of Eligard, the patient experienced fall, hip fracture so placed in a prosthesis on the right side, right wrist fracture so placed in a cast and prescribed pills to patient, did not remember the name. the patient had been bedridden. The doctor forbids the patient to take any other medication in pills, other than the one prescribed. had tests of the fractured wrist, hip and ulcers. the results indicate that the hip was fine, but the right wrist must be kept in good condition. the patient was hospitalized for 1 week due to the fall and was currently at home. On an unspecified date of 2024, unknown after the most recent dose of Eligard, the patient experienced ulcers on buttock. used a walker to get out of bed and used a wheelchair because of not walk.

Corrective treatment reported as NOBOL and OTHER THERAPEUTIC PRODUCTS.

Action taken with Eligard treatment in response to the events were dose not changed, de-challenge and re-challenge were not applicable.

The outcome of Fall was Unknown. The outcome of Hip fracture was Unknown. The outcome of Wrist fracture was Unknown. The outcome of Foot swelling was Unknown. The outcome of Ulcer was Unknown.

Relevant test results included:
Unknown date: Blood prolactin 0.052 nanogram per millilitre per hour (Ref range: Not provided)
Unknown date: C-reactive protein 19.44 milligram per litre (Ref range: Not provided)
Unknown date: Eosinophil count: 10.1 (High) (Ref range: Not provided)

Continuation Sheet for CIOMS report

Unknown date: Haemoglobin 12.1 gram per decilitre (Ref range: Not provided)
Unknown date: Mean cell haemoglobin 31.1 gram per decilitre (Ref range: Not provided)
Unknown date: Neutrophil count: 49.5 (Low) (Ref range: Not provided)
Unknown date: Red blood cell abnormality: 4.42 (Low) (Ref range: Not provided)
Unknown date: Red blood cell abnormality: 15.3 (High) (Ref range: Not provided)
Unknown date: Red blood cell sedimentation rate 35.00 mmol/h/mg{Hb} (Ref range: Not provided)
Unknown date: X-ray: the results indicate that the hip is fine, but the right wrist
must be kept in good condition (Ref range: Not provided)

The reporter assessed the seriousness of Fall, Hip fracture and Wrist fracture as serious (Hospitalization) and did not assess the causality in relationship to Eligard. The reporter did not assess the seriousness of the remaining events and did not assess the causality in relationship to Eligard.

On 02-Apr-2025, follow-up information from Panama was received by Adium (reference number: PA-ADIUM-PA-0045-20240802) via PSP Solutions (Patients Support Program) from a consumer (non-healthcare professional) and sent to Tolmar on 03-Apr-2025. New information included: added new non-serious events of ‘ear pain' (Ear pain), ‘elevated blood neutrophils' (Neutrophil count increased), ‘high eosinophils' (Eosinophil count increased), ‘erythrocyte count 4.42 (10^3 µl)' (Red blood cell count decreased), and ‘low haemoglobin' (Haemoglobin decreased).

On an unknown date, the patient experienced elevated blood neutrophils, high eosinophils, an erythrocyte count of 4.42 (10^3 µl), and low haemoglobin.

On 02-Apr-2025, the patient had an ENT appointment on Friday for ear pain.

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.

The outcome of the event ear pain was not recovered.

The outcome of neutrophil count increased, eosinophil count increased, red blood cell count decreased and haemoglobin decreased was unknown.

The reporter did not assess the seriousness of ear pain, neutrophil count increased, eosinophil count increased, red blood cell count decreased and haemoglobin decreased.

The reporter did not provide the causality of ear pain, neutrophil count increased, eosinophil count increased, red blood cell count decreased and haemoglobin decreased in relationship to Eligard and Eligard unspecified device.

No further information is expected as the reporter did not provide consent to be contacted for follow-up.

NOTE- Please note that the treatment drug 'Unknown pills' for an unspecified indication was not coded in the database due to the absence of appropriate tabs for coding. This information has already been included in the narrative.

On 10-Jul-2025, follow up information from Panama was received by Adium (reference number: PA-ADIUM-PA-0045-20240802) via PSP Solutions (Patients Support Program) from a consumer (non-healthcare professional) and sent to Tolmar on 11-Jul-2025. New information added: Added a medical procedure and concomitant medication. Narrative was updated.

The patient's medical procedure included circumcision.

Concomitant medication included neobol spray.

No further information is expected as the reporter does not consent to be contacted for follow up.

On 15-Aug-2025, follow up information from Panama was received by Adium (reference number: PA-ADIUM-PA-0045-20240802) via PSP Solutions (Patients Support Program) from a consumer (non-healthcare professional) and sent to Tolmar on 18-Aug-2025. New information added: new non serious event ‘Interruption of Eligard' (Therapy interrupted) was added, start date of prostate cancer, end date of Eligard and Xtandi, action taken was changed from dose not changed to drug withdrawn. Narrative was updated.

It was reported that, onset date of medical history Prostate Cancer was from 2005.

On an unknown date of Jun-2025, the patient had therapy interruption for Eligard and Xtandi. It was also reported that they were waiting for the test results to determine if treatment should continue and patient ID (local form) was corrected.

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

The outcome of therapy interruption was unknown.

The reporter did not assess the seriousness of therapy interrupted.

Continuation Sheet for CIOMS report

The reporter did not provide the causality of therapy interrupted in relationship to Eligard and Terumo needle pre-connected syringe.

The patient or family member or other non-healthcare professional agreed to be contacted for future follow-up and to contact their treating physician.

Listedness of events fall, hip fracture, wrist fracture, peripheral swelling, ulcer and dizziness retained as per previous assessment.

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

Neutrophil count increased>Eligard>Unlisted as per CCDS>07-Nov-2024
Neutrophil count increased>Eligard>Unlisted as per USPI>Feb-2025
Neutrophil count increased>Eligard unspecified device>Unlisted as per USPI>Feb-2025
Neutrophil count increased>Eligard>Unlisted as per Canadian monograph>02-Apr-2025

Haemoglobin decreased>Eligard>listed as per CCDS>07-Nov-2024
Haemoglobin decreased>Eligard>listed as per USPI>Feb-2025
Haemoglobin decreased>Eligard unspecified device>listed as per USPI>Feb-2025
Haemoglobin decreased>Eligard>listed as per Canadian monograph>02-Apr-2025

Red blood cell count decreased>Eligard>listed as per CCDS>07-Nov-2024
Red blood cell count decreased>Eligard>listed as per USPI>Feb-2025
Red blood cell count decreased>Eligard unspecified device>listed as per USPI>Feb-2025
Red blood cell count decreased>Eligard>listed as per Canadian monograph>02-Apr-2025

Eosinophil count increased>Eligard>Unlisted as per CCDS>07-Nov-2024
Eosinophil count increased>Eligard>Unlisted as per USPI>Feb-2025
Eosinophil count increased>Eligard unspecified device>Unlisted as per USPI>Feb-2025
Eosinophil count increased>Eligard>listed as per Canadian monograph>02-Apr-2025

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

Company Remarks (Sender's Comments) :

Evaluator Comment (Tolmar): This 91 years old male patient had Fall (Fall), Hip fracture (Hip fracture), Wrist fracture (Right wrist fracture), Peripheral swelling (Foot swelling and ugly things came out as if it was a rotten foot), Ulcer (ulcers on buttock) and Dizziness (feeling dizzy) during Eligard (Leuprolide acetate) 45 milligram therapy for Prostate cancer. XTANDI was also considered as suspect. Tolmar maintained seriousness of the events Fall, Hip fracture and Wrist fracture as hospitalization, and assessed the remaining events as non-serious since there was no immediate jeopardy to patient and they did not meet ICH seriousness criteria. Dizziness was 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 events, known safety profile of the drug and inconsistency with drug properties. Fall led to fracture of hip and wrist. Elderly age was a risk factor.

FU added event of ear pain (‘ear pain'), red blood cell count decreased (‘erythrocyte count 4.42 (10^3 µl)'), haemoglobin decreased (low haemoglobin'), eosinophil count increased (‘high eosinophils') and neutrophil count increased (‘elevated blood neutrophils') during Eligard (leuprolide acetate) 45 mg therapy for prostate cancer. Tolmar assessed the reported events as non-serious since they did not meet the ICH seriousness criteria and are not IME events. Event haemoglobin decreased and red blood cell count decreased were assessed as related to Eligard (drug) considering the known pharmacological profile of the drug. Underlying prostate cancer, elderly age of patient and co-suspect XTANDI could be the possible risk factor for the reported events. Events eosinophil count increased, neutrophil count increased and ear pain were assessed as not related to Eligard (drug) considering the inconsistency with product safety profile. All the FU added events were assessed as not related to device component of Eligard.

FU added event of therapy interrupted (Interruption of Eligard). Tolmar assessed the reported event as non-serious since it did not meet the ICH seriousness criteria. The causality of event therapy interrupted was assessed as not related to suspect Eligard(drug and device) as the event occurred with the product due to human action rather than due to drug.

Additional Information (Continuation...)

Lab Result :

Test Name	Test Date	Test Result	Normal Value

Continuation Sheet for CIOMS report

C-REACTIVE PROTEIN	Unknown	19.44 milligram per litre	
EOSINOPHIL	Unknown		
ERYTHROCYTE COUNT	Unknown		
ERYTHROCYTE DISTRIBUTION WIDTH	Unknown		
ERYTHROCYTE SEDIMENTATION RATE	Unknown	35.00 millimole per hour per milligram of hemoglobin	
HCM /CHCM CONCENTRATION	Unknown	31.1 gram per decilitre	
HOMOGLOBIN	Unknown	12.1 gram per decilitre	
NEUTROPHILS	Unknown		
PROLACTIN	Unknown	0.052 nanogram per millilitre per hour	
X-RAY	Unknown		

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

2) Test Name: EOSINOPHIL

Result Unstructured Data (free text) : 10.1 (High)

Test Date: Unknown

3) Test Name: ERYTHROCYTE COUNT

Result Unstructured Data (free text) : 4.42 (Low)

Test Date: Unknown

4) Test Name: ERYTHROCYTE DISTRIBUTION WIDTH

Result Unstructured Data (free text) : 15.3 (High)

Test Date: Unknown

8) Test Name: NEUTROPHILS

Result Unstructured Data (free text) : 49.5 (Low)

Test Date: Unknown

10) Test Name: X-RAY

Result Unstructured Data (free text) : the results indicate that the hip is fine, but the right wrist must be kept in good condition

Test Date: Unknown

Lab Comments :

1) Test Name : C-REACTIVE PROTEIN

Lab Comments : High

2) Test Name : EOSINOPHIL

Lab Comments : 10.1 (High)

3) Test Name : ERYTHROCYTE COUNT

Lab Comments : 4.42 (Low)

4) Test Name : ERYTHROCYTE DISTRIBUTION WIDTH

Lab Comments : 15.3 (High)

5) Test Name : ERYTHROCYTE SEDIMENTATION RATE

Lab Comments : High

6) Test Name : HCM /CHCM CONCENTRATION

Lab Comments : Low

7) Test Name : HOMOGLOBIN

Lab Comments : Low

Continuation Sheet for CIOMS report

8) Test Name : NEUTROPHILS

Lab Comments : 49.5 (Low)

9) Test Name : PROLACTIN

Lab Comments : High

10) Test Name : X-RAY

Lab Comments : the results indicate that the hip is fine, but the right wrist must be kept in good condition

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

Product-Reaction Level

1) Drug	:	Eligard® (Leuprolide acetate)
Active Substance	:	1) Leuprolide acetate
Drug Characterization	:	Suspect
Form Strength	:	1) 45 Milligram
		2) 45 Milligram
Form of Admin	:	1) Injection
		2) Injection
Lot Number	:	1) Unknown
Daily Dose	:	(45 milligram(s), 1 in 6 Month)
		(45 milligram(s), 1 in 6 Month)
Route of Admin	:	1) Subcutaneous
		2) Subcutaneous
Indications	:	1) Prostate cancer [10060862 - Prostate cancer]
Therapy Dates	:	1) From : 14/Jun/2021 To :/Jun/2025
		2) From : /Aug/2024 To :Unknown
Therapy Duration	:	1) 1449 Days
Action(s) Taken With Drug	:	Unknown

Causality

1) FALL (Fall - 10016173, Fall - 10016173)

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

2) HIP FRACTURE (Hip fracture - 10020100, Hip fracture - 10020100)

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

3) RIGHT WRIST FRACTURE (Wrist fracture - 10048049, Wrist fracture - 10048049)

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

4) FOOT SWELLING AND UGLY THINGS CAME OUT AS IF IT WAS A ROTTEN FOOT (Swelling of feet - 10042693, Peripheral swelling - 10048959)

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

5) ULCERS ON BUTTOCK (Amebic skin ulceration - 10001925, Amoebic skin ulcer - 10001992)

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

6) EAR PAIN (Ear pain - 10014020, Ear pain - 10014020)

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

7) ELEVATED BLOOD NEUTROPHILS (Neutrophil count increased - 10029368, Neutrophil count increased - 10029368)

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

Continuation Sheet for CIOMS report

ReChallenge : Not Applicable

8) Interruption of Eligard (Therapy interrupted - 10066377, Therapy interrupted - 10066377)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

9) HIGH EOSINOPHILS (Eosinophil count high - 10014944, Eosinophil count increased - 10014945)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

10) LOW HAEMOGLOBIN (Haemoglobin decreased - 10018884, Haemoglobin decreased - 10018884)
Causality as per reporter : Not Reported
Causality as per Mfr : Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

11) ERYTHROCYTE COUNT 4.42 (10^3 ML) (RBC decreased - 10037926, Red blood cell count decreased - 10038153)
Causality as per reporter : Not Reported
Causality as per Mfr : Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

12) FEELING DIZZY (Dizziness - 10013573, Dizziness - 10013573)
Causality as per reporter : Not Reported
Causality as per Mfr : Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) FALL
CORE UnLabeled
2) HIP FRACTURE
CORE UnLabeled
3) RIGHT WRIST FRACTURE
CORE UnLabeled
4) FOOT SWELLING AND UGLY THINGS CAME OUT AS IF IT WAS A ROTTEN FOOT
CORE UnLabeled
5) ULCERS ON BUTTOCK
CORE
6) EAR PAIN
CORE UnLabeled
7) ELEVATED BLOOD NEUTROPHILS
CORE UnLabeled
8) Interruption of Eligard
CORE UnLabeled
9) HIGH EOSINOPHILS
CORE UnLabeled
10) LOW HAEMOGLOBIN
CORE Labeled
11) ERYTHROCYTE COUNT 4.42 (10^3 ML)
CORE Labeled
12) FEELING DIZZY
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
Route of Admin : 1) Subcutaneous
Indications : 1) Prostate cancer [10060862 - Prostate cancer]
Action(s) Taken With Drug : Not applicable

Causality

1) FALL (Fall - 10016173, Fall - 10016173)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable

Continuation Sheet for CIOMS report

ReChallenge : Not Applicable

2) HIP FRACTURE (Hip fracture - 10020100, Hip fracture - 10020100)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

3) RIGHT WRIST FRACTURE (Wrist fracture - 10048049, Wrist fracture - 10048049)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

4) FOOT SWELLING AND UGLY THINGS CAME OUT AS IF IT WAS A ROTTEN FOOT (Swelling of feet - 10042693, Peripheral swelling - 10048959)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

5) ULCERS ON BUTTOCK (Amebic skin ulceration - 10001925, Amoebic skin ulcer - 10001992)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

6) EAR PAIN (Ear pain - 10014020, Ear pain - 10014020)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

7) ELEVATED BLOOD NEUTROPHILS (Neutrophil count increased - 10029368, Neutrophil count increased - 10029368)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

8) Interruption of Eligard (Therapy interrupted - 10066377, Therapy interrupted - 10066377)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

9) HIGH EOSINOPHILS (Eosinophil count high - 10014944, Eosinophil count increased - 10014945)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

10) LOW HAEMOGLOBIN (Haemoglobin decreased - 10018884, Haemoglobin decreased - 10018884)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

11) ERYTHROCYTE COUNT 4.42 (10^3 ML) (RBC decreased - 10037926, Red blood cell count decreased - 10038153)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

12) FEELING DIZZY (Dizziness - 10013573, Dizziness - 10013573)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) FALL
CORE
2) HIP FRACTURE
CORE
3) RIGHT WRIST FRACTURE
CORE
4) FOOT SWELLING AND UGLY THINGS CAME OUT AS IF IT WAS A ROTTEN FOOT
CORE

Continuation Sheet for CIOMS report

5) ULCERS ON BUTTOCK
CORE
6) EAR PAIN
CORE
7) ELEVATED BLOOD NEUTROPHILS
CORE
8) Interruption of Eligard
CORE
9) HIGH EOSINOPHILS
CORE
10) LOW HAEMOGLOBIN
CORE
11) ERYTHROCYTE COUNT 4.42 (10^3 ML)
CORE
12) FEELING DIZZY
CORE

3) Drug : XTANDI
Active Substance : 1) ENZALUTAMIDE
Drug Characterization : Suspect
Form Strength : 1) 160 Milligram
Daily Dose : (160 milligram(s), 1 in 1 Day)
Route of Admin : 1) Oral
Indications : 1) Prostate cancer [10060862 - Prostate cancer]
Therapy Dates : 1) From : To :/Jun/2025
Action(s) Taken With Drug : Unknown

Causality

1) FALL (Fall - 10016173, Fall - 10016173)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

2) HIP FRACTURE (Hip fracture - 10020100, Hip fracture - 10020100)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

3) RIGHT WRIST FRACTURE (Wrist fracture - 10048049, Wrist fracture - 10048049)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

4) FOOT SWELLING AND UGLY THINGS CAME OUT AS IF IT WAS A ROTTEN FOOT (Swelling of feet - 10042693, Peripheral swelling - 10048959)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

5) ULCERS ON BUTTOCK (Amebic skin ulceration - 10001925, Amoebic skin ulcer - 10001992)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

6) EAR PAIN (Ear pain - 10014020, Ear pain - 10014020)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

7) ELEVATED BLOOD NEUTROPHILS (Neutrophil count increased - 10029368, Neutrophil count increased - 10029368)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

8) Interruption of Eligard (Therapy interrupted - 10066377, Therapy interrupted - 10066377)
Causality as per reporter : Not Reported
DeChallenge : Not applicable
ReChallenge : Not Applicable

Continuation Sheet for CIOMS report

9) HIGH EOSINOPHILS (Eosinophil count high - 10014944, Eosinophil count increased - 10014945)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

10) LOW HAEMOGLOBIN (Haemoglobin decreased - 10018884, Haemoglobin decreased - 10018884)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

11) ERYTHROCYTE COUNT 4.42 (10^3 ML) (RBC decreased - 10037926, Red blood cell count decreased - 10038153)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

12) FEELING DIZZY (Dizziness - 10013573, Dizziness - 10013573)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

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

Dosage Text :

Drug 1 :Eligard®

1) 45 milligram, q 6 month

2) 45 milligram, q 6 month

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

1). Drug : CEFALMIN [CEFRADINE]
Active Substance : 1) CEFRADINE
Form Strength :
Daily Dose : 1) (400 milligram(s))
Indications : 1) Product used for unknown indication [10070592 - Product used for unknown indication]
Dosage Text : 1) take 1 in the morning and 1 in the evening

2). Drug : ENALAPRIL
Active Substance : 1) ENALAPRIL
Form Strength :
Indications : 1) high blood pressure [10020772 - Hypertension]

3). Drug : NORBAX M
Active Substance : 1) METRONIDAZOLE BENZOATE
2) NORFLOXACIN
Form Strength :
Indications : 1) high blood pressure [10020772 - Hypertension]

4). Drug : ATORVASTATIN
Active Substance : 1) ATORVASTATIN
Form Strength :
Indications : 1) Product used for unknown indication [10070592 - Product used for unknown indication]

5). Drug : Neobol spray
Active Substance : 1) CLOSTEBOL ACETATE
2) NEOMYCIN SULFATE
Form Strength :
Form of Admin : 1) Spray (not inhalation)
Daily Dose :
Indications : 1) ulcer [10045285 - Ulcer]

23. OTHER RELEVANT HISTORY (Continuation...)

Continuation Sheet for CIOMS report

2) CIRCUMCISION SURGERY (10009199 , Circumcision) (09/Jul/2025 - 11/Jul/2025) (Continuing : NO)

3) HIGH PRESSURE (10005750 , Blood pressure increased)

4) WHEELCHAIR (10047920 , Wheelchair user)

5) PROSTHESIS ON THE RIGHT SIDE (10053669 , Prosthesis user)

6) WALKER (10050809 , Walker user)

7) FRACTURED HIS RIGHT WRIST, SO THEY PLACED HIM A CAST (10050305 , Cast application)

Past Therapy (ies)

Product Name	:	CALUTOL
Indication	:	Prostate cancer (10060862)
Start Date	:	
Stop Date	:	