SUSPECT ADVERSE REACTION REPORT

PA-Tolmar-TLM-2025-01013

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
W-P	PANAMA	08	Apr	1944	81	Male	09	Apr	2025

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

1) Hospitalized for multiple cerebral ischemias/ her father has been hospitalized since April 2025 (Cerebral ischemia (10008121), Cerebral ischaemia (10008120))
(09/Apr/2025 -) - Not Recovered/Not Resolved/Ongoing
2) Fever (Fever (10016558), Pyrexia (10037660))
(12/May/2025 -) - Unknown
3) Fainting after ingestion of Xtandi (Fainting (10016169), Syncope (10042772))
(12/May/2025 -) - Unknown
4) Blood pressure 64/34 (Blood pressure low (10005753), Hypotension (10021097))
(12/May/2025 -) - 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) (Injection)(Unknown)

Cont..

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

15. DAILY DOSE(S)

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

Cont..

16. ROUTE(S) OF ADMINISTRATION

1) 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) (01/Apr/2024 - ongoing)	

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

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-2025-01013
24c. DATE RECEIVED BY MANUFACTURER	24d. REPORT SOURCE
04/Jun/2025	☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT	25a. REPORT TYPE
14/Jun/2025	☐ INITIAL ☑ FOLLOWUP

= Continuation attached sheet(s)..

Continuation Sheet for CIOMS report

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

5) Completely decompensated (Chronic disease (10076311), Chronic disease (10076311)(15/Apr/2025 -) - Not Recovered/Not Resolved/Ongoing)

6) Completely decompensated (Condition worsened (10076326), Condition aggravated (10010264)(15/Apr/2025 -) - Not Recovered/Not Resolved/Ongoing)

7) High blood sugar/ Sugar 225 (Blood glucose increased (10005557), Blood glucose increased (10005557)(15/Apr/2025 -) - Not Recovered/Not Resolved/Ongoing)

8) due to her condition she has not been able to apply her Eligard dose that corresponded to the month of May 2025, (Intentional dose omission (10079221), Intentional dose omission (10079221)(/May/2025 -) - Unknown)

Event Description :

This Invalid case report from PANAMA was received by Adium PSP - Prevenfuturo (reference number: PA-ADIUM-PA-0023-20250317) on 17-MAR-2025 from Consumer/Other Non-Health Prof and sent to Tolmar on 18-MAR-2025.

This report was assessed as invalid as no adverse event was reported. The reported term was not considered an adverse event because the reason for the surgery was not provided.

On 21-Apr-2025, follow up information was received by Adium (reference number: PA-ADIUM-PA-0023-20250317) from a consumer (family member) and sent to Tolmar on 22-Apr-2025. New information included: Case upgraded from invalid to valid. New serious (hospitalization and medically significant) events added as “High blood sugar” (Blood glucose increased) and ‘Completely decompensated' (Chronic disease and condition aggravated). Lab investigation added as “blood glucose". Action taken updated.

The patient's medical history was unknown and current condition included prostate cancer.

Concomitant medications were Xtandi (enzalutamide).

On 13-Mar-2025, the patient had a toe to be amputated.

On Tuesday, 18-Mar-2024, the discharge from the hospital was anticipated. No further details were provided.

On 01-Apr-2024, the patient began receiving Eligard 45 mg every 6 months via subcutaneous route for prostate cancer (Lot numbers and expiration dates were unknown).

On 15-Apr-2025, the patient had been hospitalized due to elevated blood sugar level and was found to be completely decompensated. No further details were provided.

Corrective treatment was unknown.

Relevant test results included:
On 15-Apr-2025: blood glucose: high blood sugar (Ref range: not provided).

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

The outcome of blood glucose increased, chronic disease and condition aggravated was not recovered.

The reporter assessed the seriousness of blood glucose increased, chronic disease and condition aggravated as serious (hospitalization).

The reporter did not provide the causality of blood glucose increased, chronic disease and condition aggravated in relationship to Eligard and Eligard Unspecified Device.

On 12-May-2025, follow up information was received by Adium via Patient Support Program (reference number: PA-ADIUM-PA-0023-20250317) from a consumer (Patient's daughter/family member/ non-healthcare professional) and sent to Tolmar on 13-May-2025. New information included: Serious event of ‘Hospitalized for multiple cerebral ischemias' (Cerebral ischaemia) (Life-threatening; disability; hospitalization) was added. Added new serious (hospitalisation) events of ‘Fainting after ingestion of Xtandi' (Syncope), ‘Blood pressure 64/34' (Hypotension), ‘fever' (Pyrexia) and non-serious event ‘due to her condition she has not been able to apply her Eligard dose that corresponded to the month of May-2025 (Intentional dose omission), previous reported serious event Blood glucose increased - verbatim was updated High blood sugar from High blood sugar/ Sugar 225 and outcome was updated from not recovered to unknown and additional seriousness of hospitalisation was added . medical history was added Laboratory tests were added. Xtandi was updated to co-suspect.

Medical history included hypotension and blood glucose increased

On 09-Apr-2025, the patient was hospitalized due to multiple cerebral ischemia.

Continuation Sheet for CIOMS report

On an unknown date in 2025, during the hospitalization, the patient underwent CT scan and MRI. But through the MRI only he was confirmed for cerebral ischemia.

On 09-May-2025, the patient was discharged from the hospital.

On 12-May-2025, the patient was again hospitalized due to fever, low blood pressure, high sugar and due to fainting after ingestion of Xtandi.

On an unknown date in May-2025, the patient was intended to receive Eligard but due to his condition he was not able to apply Eligard dose that corresponded to the month.

The patients' daughter reported that patient continues with both treatments of Eligard and Xtandi, but she does not know when the last dose of Eligard was given as it was 6 months ago (Expiration date and lot number is not reported). She confirmed that the patient had already suffered from low blood pressure and high blood sugar before starting Eligard and Xtandi.

Further corrective treatment was reported.

Relevant test results included:
On an unknown date in 2025: CT scan: Unknown (Ref. range: Not provided).
On an unknown date in 2025: MRI: The patient was diagnosed with cerebral ischemia (Ref. range: Not provided).
On 12-May-2025: Blood glucose: Sugar 225 (Ref. range: Not 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 syncope, hypotension, blood glucose increased, cerebral ischaemia, pyrexia and intentional dose omission was unknown.

The reporter assesses the seriousness of syncope, hypotension, blood glucose increased, cerebral ischaemia, pyrexia as serious (hospitalisation) and did not assess for intentional dose omission.

The reporter did not provide the causality of syncope, hypotension, blood glucose increased, cerebral ischaemia, pyrexia, intentional dose omission in relationship to Eligard and Eligard unspecified device.

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

On 04-Jun-2025, follow up information was received by Adium via Patient Support Program (reference number: PA-ADIUM-PA-0023-20250317) from a consumer (Patient's daughter/family member/ non-healthcare professional) and sent to Tolmar on 05-Jun-2025. New information included: outcome of event 'Hospitalized for multiple cerebral ischemias' was updated from 'unknown' to 'unresolved / ongoing', seriousness criteria of 'fever' updated to hospitalization and causal relationship was provided by reporter.

On 01-Apr-2024, the patient began receiving Eligard 45 mg every 6 months via subcutaneous route for prostate cancer (Lot numbers and expiration dates were unknown).

On an unknown date, patient was hospitalized due to multiple cerebral ischemia, and he remains hospitalized.

Corrective treatment includes hospitalization.

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

The outcome of cerebral ischemia was not recovered.

The reporter assesses the seriousness of cerebral ischaemia as serious (hospitalisation) (permanent damage) (life threatening).

The reporter provided the causality of syncope, hypotension, blood glucose increased, cerebral ischaemia, pyrexia, intentional dose omission, blood glucose increased, chronic disease and condition aggravated in relationship to Eligard and Eligard unspecified device.

On 09-Jun-2025, follow up information was received by Adium via Patient Support Program (reference number: PA-ADIUM-PA-0023-20250317) from a consumer (Patient's daughter/family member/ non-healthcare professional) and sent to Tolmar on 10-Jun-2025.

On 09-Apr-2025, the patient was hospitalized, and he was still in the hospital. No further details were mentioned.

Corrective treatment includes hospitalization.

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

The outcome of event was not recovered.

The reporter assesses the seriousness of event as serious (hospitalisation).

Continuation Sheet for CIOMS report

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

On 11-Jun-2025.follow up information was received by Adium via Patient Support Program (reference number: PA-ADIUM-PA-0023-20250317 (5)) from a consumer from Safety tool of the Patient Support Program "ASOFARMA A TU LADO" The event form corrected and confirmed Eligard at a dose of 45 mg every 6 months by subcutaneous administration.

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

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

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

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

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

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

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

Intentional dose omission >Eligard® >unlisted as per CCDS Eligard®> 7-Nov-2024
Intentional dose omission > Eligard® >unlisted as per Canadian Monograph Eligard®> 2-Apr-2025
Intentional dose omission > Eligard®>unlisted as per USPI Eligard®>Feb-2025
Intentional dose omission > Eligard unspecified device>unlisted as per USPI Eligard®>Feb-2025

Company Remarks (Sender's Comments) :

Evaluator comment (Tolmar): This is regarding an elderly 81-year-old male patient who experienced blood glucose increased (high blood sugar), chronic disease and condition aggravated (completely decompensated) during Eligard (leuprolide acetate) 45 mg therapy for prostate cancer. Tolmar assessed the reported event as serious (hospitalisation and medically significant) since the patient was hospitalised in response to events. The reported event blood glucose increased is assessed as not related Eligard (drug) considering the medical history of blood glucose increased, elderly age and co-existing events chronic disease completely decompensated. The events chronic disease and condition aggravated could not be assessed conclusively for events chronic disease and condition aggravated for drug Eligard due to lack of sufficient information regarding clinical details, exact condition that was decompensated, relevant medical history if any, concomitant medication details, lab reports if any. All the reported events were assessed as not related to device component of Eligard.

Fu added events Cerebral ischaemia (Hospitalized for multiple cerebral ischemias), Syncope (Fainting after ingestion of Xtandi), Hypotension (Blood pressure 64/34), Pyrexia (fever) and Intentional dose omission (due to her condition she has not been able to apply her Eligard dose that corresponded to the month of May-2025). Tolmar assessed the event Cerebral ischaemia as serious (Life-threatening; disability; hospitalization) as it lead to hospitalisation, resulted in disability and life-threatening nature of the event, events syncope, hypotension, pyrexia resulted in hospitalisation and intentional dose omission was assessed as non-serious since it did not meet the ICH seriousness criteria.
The causality of event cerebral ischaemia was assessed as not related to suspect Eligard(drug and device) considering the nature of event, aetiopathogenesis and medical history of blood glucose increased prior to starting Eligard and advancing age could be risk factors for the event. The causality of event syncope was assessed as not related to suspect Eligard(drug and device) as per available information it occurred after ingestion of Xtandi. The causality of event hypotension and pyrexia was assessed as not related to suspect Eligard as hypotension could be due to coexisting

Continuation Sheet for CIOMS report

events, patient had history of hypotension prior to starting Eligard which could be risk factor, pyrexia could be due to co-existing events, elderly age and immunosuppressed state of patient due to underlying prostate cancer could be risk factors. The causality of event intentional dose omission was assessed as not related to suspect Eligard(drug and device) as it is due to human action rather than due to drug.

Additional Information (Continuation...)

Lab Result :

Test Name	Test Date	Test Result	Normal Value
BLOOD GLUCOSE	15/Apr/2025		
BLOOD PRESSURE	12/May/2025		
CT SCAN	//2025		
MRI	//2025		
SUGAR	12/May/2025		

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

1) Test Name: BLOOD GLUCOSE

Result Unstructured Data (free text) : High blood sugar

Test Date: 15/Apr/2025

2) Test Name: BLOOD PRESSURE

Result Unstructured Data (free text) : Blood pressure 64/34

Test Date: 12/May/2025

3) Test Name: CT SCAN

Result Unstructured Data (free text) : Unknown

Test Date: //2025

4) Test Name: MRI

Result Unstructured Data (free text) : The patient was diagnosed with cerebral ischemia

Test Date: //2025

5) Test Name: SUGAR

Result Unstructured Data (free text) : Sugar 225

Test Date: 12/May/2025

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
- Lot Number : 1) Unknown
- Daily Dose : (45 milligram(s), 1 in 6 Month)
- Route of Admin : 1) Subcutaneous
- Indications : 1) Prostate cancer [10060862 - Prostate cancer]
- Therapy Dates : 1) From : 01/Apr/2024 To :Continuing
- Action(s) Taken With Drug : Dose not changed

Causality

1) Hospitalized for multiple cerebral ischemias/ her father has been hospitalized since April 2025 (Cerebral ischemia - 10008121, Cerebral ischaemia - 10008120)
- Causality as per reporter : Not Reported
- Causality as per Mfr : Not Related
- DeChallenge : Not applicable
- ReChallenge : Not Applicable

2) Fever (Fever - 10016558, Pyrexia - 10037660)

Continuation Sheet for CIOMS report

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

3) Fainting after ingestion of Xtandi (Fainting - 10016169, Syncope - 10042772)
Causality as per reporter : Not Related
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

4) Blood pressure 64/34 (Blood pressure low - 10005753, Hypotension - 10021097)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

5) Completely decompensated (Chronic disease - 10076311, Chronic disease - 10076311)
Causality as per reporter : Not Reported
Causality as per Mfr : Not assessable
DeChallenge : Not applicable
ReChallenge : Not Applicable

6) Completely decompensated (Condition worsened - 10076326, Condition aggravated - 10010264)
Causality as per reporter : Not Reported
Causality as per Mfr : Not assessable
DeChallenge : Not applicable
ReChallenge : Not Applicable

7) High blood sugar/ Sugar 225 (Blood glucose increased - 10005557, Blood glucose increased - 10005557)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

8) due to her condition she has not been able to apply her Eligard dose that corresponded to the month of May 2025, (Intentional dose omission - 10079221, Intentional dose omission - 10079221)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) Hospitalized for multiple cerebral ischemias/ her father has been hospitalized since April 2025
CORE UnLabeled

2) Fever
CORE Labeled

3) Fainting after ingestion of Xtandi
CORE Labeled

4) Blood pressure 64/34
CORE Labeled

5) Completely decompensated
CORE UnLabeled

6) Completely decompensated
CORE UnLabeled

7) High blood sugar/ Sugar 225
CORE Labeled

8) due to her condition she has not been able to apply her Eligard dose that corresponded to the month of May 2025,
CORE UnLabeled

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) Hospitalized for multiple cerebral ischemias/ her father has been hospitalized since April 2025 (Cerebral ischemia - 10008121, Cerebral ischaemia - 10008120)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related

Continuation Sheet for CIOMS report

DeChallenge : Not applicable
ReChallenge : Not Applicable

2) Fever (Fever - 10016558, Pyrexia - 10037660)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

3) Fainting after ingestion of Xtandi (Fainting - 10016169, Syncope - 10042772)
Causality as per reporter : Not Related
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

4) Blood pressure 64/34 (Blood pressure low - 10005753, Hypotension - 10021097)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

5) Completely decompensated (Chronic disease - 10076311, Chronic disease - 10076311)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

6) Completely decompensated (Condition worsened - 10076326, Condition aggravated - 10010264)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

7) High blood sugar/ Sugar 225 (Blood glucose increased - 10005557, Blood glucose increased - 10005557)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

8) due to her condition she has not been able to apply her Eligard dose that corresponded to the month of May 2025, (Intentional dose omission - 10079221, Intentional dose omission - 10079221)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) Hospitalized for multiple cerebral ischemias/ her father has been hospitalized since April 2025
CORE
2) Fever
CORE
3) Fainting after ingestion of Xtandi
CORE
4) Blood pressure 64/34
CORE
5) Completely decompensated
CORE
6) Completely decompensated
CORE
7) High blood sugar/ Sugar 225
CORE
8) due to her condition she has not been able to apply her Eligard dose that corresponded to the month of May 2025,
CORE

3) Drug : XTANDI
Active Substance : 1) ENZALUTAMIDE
Drug Characterization : Suspect
Form Strength : 1) 40 Milligram
Form of Admin : 1) Capsule
Lot Number : 1) Unknown
2) Unknown
Daily Dose : (160 milligram(s), 1 in 1 Day)
Route of Admin : 1) Oral

Continuation Sheet for CIOMS report

Indications : 1) Prostate cancer [10060862 - Prostate cancer]
Therapy Dates : 1) From : 01/Apr/2024 To :Continuing
2) From : /May/2025 To :Continuing
Action(s) Taken With Drug : Dose not changed

Causality

1) Hospitalized for multiple cerebral ischemias/ her father has been hospitalized since April 2025 (Cerebral ischemia - 10008121, Cerebral ischaemia - 10008120)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

2) Fever (Fever - 10016558, Pyrexia - 10037660)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

3) Fainting after ingestion of Xtandi (Fainting - 10016169, Syncope - 10042772)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

4) Blood pressure 64/34 (Blood pressure low - 10005753, Hypotension - 10021097)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

5) Completely decompensated (Chronic disease - 10076311, Chronic disease - 10076311)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

6) Completely decompensated (Condition worsened - 10076326, Condition aggravated - 10010264)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

7) High blood sugar/ Sugar 225 (Blood glucose increased - 10005557, Blood glucose increased - 10005557)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

8) due to her condition she has not been able to apply her Eligard dose that corresponded to the month of May 2025, (Intentional dose omission - 10079221, Intentional dose omission - 10079221)
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) ELIGARD 45 MG x 1 LIO x 1 JER

Drug 3 :XTANDI

1) 40 milligram, qid XTANDI 40 MG x 120 CAP x 30 FND

23. OTHER RELEVANT HISTORY (Continuation...)

2) LOW BLOOD PRESSURE (10024895 , Low blood pressure)

3) HIGH BLOOD SUGAR (10005557 , Blood glucose increased)