SUSPECT ADVERSE REACTION REPORT

TLM-2025-01839; PA-TOLMAR, INC.-22PA035269

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
F-O	PANAMA	19	Jan	1937	85	Male	11	Jun	2022

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

1) HIGH BLOOD PRESSURE (Blood pressure high (10005747), Hypertension (10020772))
(11/Jun/2022 - 01/May/2025) - Fatal
2) Stroke, which caused significant sequelae (Stroke (10042244), Cerebrovascular accident (10008190))
(- 01/May/2025) - Fatal
3) Heart attack due to Alzheimer's (Heart attack (10019250), Myocardial infarction (10028596))
(- 01/May/2025) - Fatal
4) Heart attack due to Alzheimer's (Progression of Alzheimer's disease (10066571), Dementia Alzheimer's type (10012271))
(- 01/May/2025) - Fatal

Cont..

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

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

II. SUSPECT DRUG(S)INFORMATION

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

1) Eligard® (Leuprolide acetate, Leuprolide acetate) (Suspect) (Injection)(Asked but Unknown)(Asked but Unknown) (Unknown)

Cont..

15. DAILY DOSE(S)

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

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

Cont..

16. ROUTE(S) OF ADMINISTRATION

1) Subcutaneous
2) Subcutaneous

Cont..

17. INDICATION(S) FOR USE

1) Prostate cancer [10060862 - Prostate cancer]

Cont..

18. THERAPY DATE(S) (from/to)

1) (/Mar/2022 - Asked but Unknown)

19. THERAPY DURATION

20. DID EVENT ABATE AFTER STOPPING DRUG? [ ] YES [ ] NO [x] NA

21. DID EVENT REAPPEAR AFTER REINTRODUCTION [ ] YES [ ] NO [x] NA

(NA : Not Applicable)

III. CONCOMITANT DRUG(S) AND HISTORY

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

1)ANTIBIOTICS(OTHER THERAPEUTIC PRODUCTS)

Cont..

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

1) PROSTATE CANCER (10060862, Prostate cancer) (Masked -) (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
debbie.maierhofer@tolmar.comand+1-4129158447

Study Information
Study Name: NA
EudraCT Number:
Protocol No.: NA
Center No.:
Subject Id :

24.REPORT NULLIFIED [ ] YES [ ] NO

24b. MFR CONTROL NO.

TLM-2025-01839; PA-TOLMAR,

24c. DATE RECEIVED BY MANUFACTURER

12/May/2025

24d. REPORT SOURCE [x] STUDY [ ] LITERATURE [ ] HEALTH PROFESSIONAL

DATE OF THIS REPORT

22/May/2025

25a. REPORT TYPE [x] INITIAL [ ] FOLLOWUP

= Continuation attached sheet(s)..

Continuation Sheet for CIOMS report

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

5) LOW POTASSIUM (Potassium decreased (10036443), Blood potassium decreased (10005724)(11/Jun/2022 -) - Recovering/Resolving)

6) CHEST PNEUMONIA (Pneumonia (10035664), Pneumonia (10035664)(11/Jun/2022 -) - Recovering/Resolving)

7) HE WAS ALMOST DYING (Terminal state (10048669), Terminal state (10048669)(17/Dec/2024 -) - Not Recovered/Not Resolved/Ongoing)

8) UNABLE TO WALK (Unable to walk (10049278), Gait inability (10017581)(Asked but Unknown -) - Unknown)

9) PATIENT COULD NOT BREATHE (Breathing difficult (10006338), Dyspnoea (10013968)(Asked but Unknown -) - Not Recovered/Not Resolved/Ongoing)

10) bedridden for three years (Bedridden (10048948), Bedridden (10048948) - Unknown)

11) URINARY INFECTION (Urinary infection (10046544), Urinary tract infection (10046571)(11/Jun/2022 -) - Recovering/Resolving)

12) SPENT THE WHOLE NIGHT COMPLAINING (EVERYTHING HURT) (General body pain (10048971), Pain (10033371)(Asked but Unknown -) - Not Recovered/Not Resolved/Ongoing)

13) THE PRESSURE WAS VERY LOW (Blood pressure low (10005753), Hypotension (10021097)(Asked but Unknown -) - Not Recovered/Not Resolved/Ongoing)

14) IT FEELS VERY BITTER (Taste bitter (10043127), Dysgeusia (10013911)(Asked but Unknown -) - Unknown)

15) IT WAS INFLAMMATION BECAUSE THE PATIENT WAS IN BAD SHAPE (Inflammation NOS (10021961), Inflammation (10061218)(Asked but Unknown -) - Unknown)

16) THE PATIENT HAD NOT BEEN USING THE TOILET FOR 8 DAYS, NOT BEEN ABLE TO RELIEVE HIMSELF (Constipation (10010774), Constipation (10010774) - Not Recovered/Not Resolved/Ongoing)

Event Description :

This solicited report from Panama was received by Adium (MFR no.: PA-0060-20220617) via the Patients Support Program "ASOFARMA A TU LADO" on 15 Jun 2022 from a patient´s family member regarding an 85 years old male patient who was hospitalized due to the events urinary infection (Urinary infection), low potassium (Potassium decreased), chest pneumonia (Pneumonia) and high blood pressure (Blood pressure high), the patient was unable to walk (Unable to walk) during Eligard (leuprolide acetate) 45 mg for prostate cancer. The needle component of the constituent device was not identified in the report. The report was sent to Tolmar on 17 Jun 2022.

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

Concomitant medications included unspecified antibiotics for an unknown indication and unspecified pressure medication.

On an unspecified date, the patient began receiving Eligard 45 mg, every 6 months, subcutaneously for prostate cancer (Lot number and Expiration date not reported). On an unknown date, unspecified time after starting Eligard therapy, the patient was unable to walk and used a wheelchair.

On an unspecified date in Mar 2022, the patient received his most recent dose of Eligard 45 mg, every 6 months, subcutaneously for prostate cancer (Lot number and Expiration date not reported).

On 11 Jun 2022, the patient was hospitalized for urinary tract infection, high blood pressure, low potassium and chest pneumonia. On 15 Jun 2022, the patient was recovering and conscious, and further unspecified tests would be performed. The patient's family would communicate with the oncologist to let him know the situation and that the doctor would tell them if he would apply the Eligard treatment in September. No further information was reported.

Action taken with Eligard was dose not changed.

De-challenge and re-challenge were not applicable.

The outcome of the event unable to walk was unknown while the outcome for the remaining events was resolving.

The reporter assessed the events of urinary infection, low potassium, chest pneumonia and high blood pressure as serious (hospitalization) and did not assess the seriousness for the remaining event.

The reporter did not assess the causality regarding Eligard therapy.

Continuation Sheet for CIOMS report

On 20-DEC-2023, follow-up information was received by Adium (reference number: PA-0060-20220617) from a Patient Family Member and sent to Tolmar on 21-DEC-2023. New information included: additional reported added, new non serious event of “It feels very bitter (Taste bitter)” and updated clinical course details.

Other therapeutic products (medication for high blood pressure) was upgraded as a co-suspect.

Reportedly, the patient was being given medication for high blood pressure in capsules, given in the morning and afternoon, but the patient could not take the whole pill and to take it they dilute it in water, but the patient did not want to open his mouth to take it, because it felt very bitter, so his son put honey in his mouth with his finger so that the bitter taste of the medication went away.

Corrective treatment was not reported.

Action taken with Eligard in response to the event was Unknown.

De-challenge and re-challenge were Not applicable. The outcome of Taste bitter was Unknown.

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

On 20-DEC-2024, follow-up information was received by Adium (reference number: PA-0060-20220617) from a Patient Family Member and sent to Tolmar on 24-DEC-2024. New information included: New serious hospitalization event of almost dying (Terminal state), medically significant events of patient could not breathe (Breathing difficult), everything hurt (General body pain), the pressure was very low (Blood pressure low) and non-serious events of inflammation (Inflammation NOS), not been able to relieve himself (Constipation). Added medical history (Enema, Alzheimer's disease, Convulsions, Blood pressure abnormal), treatment drug as Oxygen, Lab data, start date of Eligard. Updated event Unable to walk from non-serious to serious medically significant.

The patient's medical history and current conditions included: Alzheimer's disease, Convulsions, Blood pressure abnormal Procedure: Enema.

On 23-JAN-2021, the patient began receiving Eligard 45 mg, every 6 months, subcutaneously for prostate cancer (Lot number and Expiration date not reported).

On an unspecified date, at an unknown amount of time after the most recent dose of Eligard, the patient experienced had not been using the toilet for 8 days (referring to the fact that the patient had not been able to relieve himself), for this reason he was given an enema, which allowed the patient to relieve himself in the afternoon and at night, but he spent the whole night complaining. On 17-DEC-2024, was hospitalized because he was almost dying, when he was admitted to the hospital, they managed to stabilize him and to get oxygen to his brain, the patient could not breathe and spent the whole night complaining everything hurt.

On an unspecified date, the patient had already been complaining for two days, doctors performed some tests (unspecified name), the doctors who were checking the patient would perform a culture test, but that could not be done because the patient had prostate problems, the reporter believed that it was inflammation because the patient was in bad shape but it was unknown because only the doctor had the information, the pressure was very low and had complications, but that the patient was already in the emergency room.

Currently (by the time of this report) the patient was in the emergency room, the doctors indicated that they would wait about 20 minutes to verify how the patient reacted, because he had been gradually receiving oxygen to the brain and the pressure went up a little, it was unknown if the patient was already recovered since the patient still receiving the treatment (not specified) to save the patient. The patient was stabilizing little by little and the patient was thin.

Corrective treatment included for breathing difficult as Oxygen and for constipation as procedure Enema. Action taken with Eligard was dose not changed. De-challenge and re-challenge were not applicable.

The outcome of Terminal state was Not Recovered/Not Resolved. The outcome of Breathing difficult was Not Recovered/Not Resolved.

The outcome of General body pain was Not Recovered/Not Resolved.

The outcome of Blood pressure low was Not Recovered/Not Resolved.

The outcome of Constipation was Not Recovered/Not Resolved.

The outcome of Inflammation NOS was Unknown.

The outcome of Unable to walk was Unknown.

Relevant test results included:
Unknown date: Blood pressure measurement: the pressure was very low (No units or values provided)
Unknown date: Laboratory test: Unknown results (No units or values provided)

The reporter assessed the event of Terminal state as serious (hospitalization) and Breathing difficult, General body pain, Blood pressure low, Unable to walk as serious (Medically significant) and did not assess the seriousness for the events Inflammation NOS, Constipation.

The reporter did not assess the causality of all events with regards to Eligard.

On 12-May-2025, follow-up information was received by Adium (reference number: PA-0060-20220617) from a consumer (Patient Family Member) (non-healthcare professional) and sent to Tolmar on 13-May-2025. New information included: Eligard last dose added, Current conditions, Treatment and concomitant drugs added. New serious events death due to "heart attack due to Alzheimer's" (Myocardial infarction) (life threatening) (disability), "heart attack due to Alzheimer's"(Dementia Alzheimer's type) (life threatening) (disability), "Stroke, which caused significant sequelae" (cerebrovascular accident)(life threatening) (disability), high blood pressure (Hypertension)(life threatening) and serious event (medically significant), “bedridden for three years” (Bedridden) were added. Action taken updated from "unknown" to "not applicable", outcome of event hypertension was updated from resolving to death.

Current conditions included depression, anxiety and brain injury.

Concomitant medications included Concor (bisoprolol), Keppra (Levetiracetam), Vitamins and other therapeutic products (medication for convulsion), other therapeutic products (medication for depression), other therapeutic products (medication for anxiety).

On 24-Oct-2024, patient received last dose of Eligard 30mg every 6 months, subcutaneously for prostate cancer (Lot number and Expiration date not reported) for prostate cancer.

On 01-May-2025, patient died due to stroke, heart attack due to Alzheimer's, Alzheimer's (Progression of Alzheimer's disease), hypertension. The patient was 88-year-old at the time of death. It was unknown if an autopsy was performed.

Corrective treatment drug includes potassium K-ion for low potassium and angiotrophin, irbesartan for high blood pressure.

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

The outcome of Myocardial infarction, Dementia Alzheimer's type, Hypertension, Cerebrovascular accident was fatal whereas of bedridden was unknown

The reporter did not assess the seriousness of Myocardial infarction, Dementia Alzheimer's type, Hypertension, Cerebrovascular accident, Bedridden.

The reporter did not provide the causality of Myocardial infarction, Dementia Alzheimer's type, Hypertension, Cerebrovascular accident, Bedridden in relationship to Eligard and Eligard unspecified device.

No follow-up queries raised.

Listedness of previously reported events were retained as previously assessed.
New events listedness:
Myocardial infarction>Eligard® >unlisted as per CCDS Eligard®> 7-Nov-2024
Myocardial infarction> Eligard® >unlisted as per Canadian Monograph Eligard®> 2-Apr-2025
Myocardial infarction> Eligard®>unlisted as per USPI Eligard®>Feb-2025
Myocardial infarction> Eligard® Unspecified Device>unlisted as per USPI Eligard®>Feb-2025

Dementia Alzheimer's type>Eligard® >unlisted as per CCDS Eligard®> 7-Nov-2024
Dementia Alzheimer's type> Eligard® >unlisted as per Canadian Monograph Eligard®> 2-Apr-2025
Dementia Alzheimer's type> Eligard®>unlisted as per USPI Eligard®>Feb-2025
Dementia Alzheimer's type> Eligard® Unspecified Device>unlisted as per USPI Eligard®>Feb-2025

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

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

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

Company Remarks (Sender's Comments) :

Evaluator comment (Tolmar): This is regarding 85-year-old male patient who was hospitalized due to the urinary tract infection (Urinary infection), low potassium (Potassium decreased), chest pneumonia (Pneumonia) and high blood pressure (Blood pressure high), the patient was unable to walk

Continuation Sheet for CIOMS report

(Unable to walk) during Eligard (leuprolide acetate) 45 mg for prostate cancer. Tolmar assessed (Urinary infection, Potassium decreased, Pneumonia and Blood pressure high as serious due to hospitalization, while event "Unable to walk" was assessed as non-serious as the event does not meet ICH seriousness criterion. Tolmar assessed Blood pressure high as related to Eligard (drug) based on temporal association and known safety profile of the drug, while it was not related to Eligard (device). Prostate cancer and age are considered as confounders. Causality of the remaining events was assessed as not related with Eligard (drug and device). Potassium decreased was likely due to use of antibiotic drugs. Urinary infection and Pneumonia were of infectious etiology likely facilitated by immunocompromised state of the patient owing to patient's malignancy. Event Unable to walk was likely consequence of multiple morbidities in this 85-year-old patient.
As per the follow up information provided patient experienced dysgeusia (it feels very bitter). Tolmar assessed the event as non-serious as it did not meet ICH seriousness criteria and no immediate jeopardy is noted. Event is considered as not related to Eligard (drug and device) as per the case context it is due to the medications patient had for high blood pressure.
Based on the follow up reported patient is in terminal state (almost dying), experienced dyspnea (patient could not breathe), pain (everything hurt), hypotension (pressure was very low), inflammation (Inflammation) and constipation (not been able to relieve himself). Tolmar assessed the events terminal state, dyspnea, pain and hypotension as serious (MS) based on their significant impact on patient's health and require significant medical intervention to prevent a serious outcome, while inflammation and constipation is a non-serious event as they did not meet ICH seriousness criteria. Events hypotension and constipation are considered as related to Eligard (drug) based on the temporal relationship and consistency of the events with product safety profile, while all other events are considered as not related to Eligard (drug) as per the etiopathogenesis of the events and their inconsistency with product safety profile. Elderly age and underlying malignancy are strong confounders.

FU added events serious events (heart attack due to Alzheimer's) Myocardial infarction (life threatening) (disability), (heart attack due to Alzheimer's) Dementia Alzheimer's type (life threatening) (disability), (Stroke, which caused significant sequelae) cerebrovascular accident (life threatening) (disability), (high blood pressure) Hypertension (life threatening) and serious event (medically significant), (bedridden for three years) Bedridden. Tolmar assessed the events Myocardial infarction, Dementia Alzheimer's type, cerebrovascular accident, hypertension as fatal as it resulted in death and bedridden was assessed as serious as the patient was bedridden for 3 years and considering the clinical impact the event could have on patient's health. The causality of the events myocardial infarction, Dementia Alzheimer's type, cerebrovascular accident and hypertension were assessed as not related to suspect Eligard(drug and device) as the events lead to patient's death, cerebrovascular accident could have occurred secondary to hypertension, inconsistency with the safety profile of the drug, hypercoagulable state and immunosuppression due to underlying prostate cancer, elderly age could be risk factors for these events. The causality of event bedridden was assessed as not related to suspect Eligard(drug and device) as it could be consequence to gait inability and elderly age could be a risk factor for the events.

Additional Information (Continuation...)

Lab Result :

Test Name	Test Date	Test Result	Normal Value
BLOOD PRESSURE	Unknown		
BLOOD PRESSURE	Unknown		
LABORATORY TEST	Unknown		
POTASSIUM	Unknown		

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

1) Test Name: BLOOD PRESSURE

Result Unstructured Data (free text) : high blood pressure
Test Date: Unknown

2) Test Name: BLOOD PRESSURE

Result Unstructured Data (free text) : the pressure was very low (no units or values provided)
Test Date: Unknown

3) Test Name: LABORATORY TEST

Result Unstructured Data (free text) : Unknown results (No units or values provided)
Test Date: Unknown

4) Test Name: POTASSIUM

Result Unstructured Data (free text) : potassium low
Test Date: Unknown

Lab Comments :

1) Test Name : BLOOD PRESSURE

Lab Comments : high blood pressure

2) Test Name : BLOOD PRESSURE

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Lab Comments : the pressure was very low (no units or values provided)

3) Test Name : LABORATORY TEST

Lab Comments : Unknown results (No units or values provided)

4) Test Name : POTASSIUM

Lab Comments : potassium low

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
Lot Number	:	1) Asked but Unknown 2) Asked but Unknown 3) Unknown
Daily Dose	:	(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
Indications	:	1) Prostate cancer [10060862 - Prostate cancer]
Therapy Dates	:	1) From : /Mar/2022 To : 2) From : 23/Jan/2021 To : 3) From : 24/Oct/2024 To :
Action(s) Taken With Drug	:	Not applicable

Causality

1) HIGH BLOOD PRESSURE (Blood pressure high - 10005747, Hypertension - 10020772)

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

2) Stroke, which caused significant sequelae (Stroke - 10042244, Cerebrovascular accident - 10008190)

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

3) Heart attack due to Alzheimer's (Heart attack - 10019250, Myocardial infarction - 10028596)

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

4) Heart attack due to Alzheimer's (Progression of Alzheimer's disease - 10066571, Dementia Alzheimer's type - 10012271)

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

5) LOW POTASSIUM (Potassium decreased - 10036443, Blood potassium decreased - 10005724)

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

6) CHEST PNEUMONIA (Pneumonia - 10035664, Pneumonia - 10035664)

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

7) HE WAS ALMOST DYING (Terminal state - 10048669, Terminal state - 10048669)

Causality as per reporter	:	Not Reported

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

8) UNABLE TO WALK (Unable to walk - 10049278, Gait inability - 10017581)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

9) PATIENT COULD NOT BREATHE (Breathing difficult - 10006338, Dyspnoea - 10013968)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

10) bedridden for three years (Bedridden - 10048948, Bedridden - 10048948)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

11) URINARY INFECTION (Urinary infection - 10046544, Urinary tract infection - 10046571)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

12) SPENT THE WHOLE NIGHT COMPLAINING (EVERYTHING HURT) (General body pain - 10048971, Pain - 10033371)
Causality as per reporter : Not Reported
Causality as per Mfr : Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

13) THE PRESSURE WAS VERY LOW (Blood pressure low - 10005753, Hypotension - 10021097)
Causality as per reporter : Not Reported
Causality as per Mfr : Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

14) IT FEELS VERY BITTER (Taste bitter - 10043127, Dysgeusia - 10013911)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

15) IT WAS INFLAMMATION BECAUSE THE PATIENT WAS IN BAD SHAPE (Inflammation NOS - 10021961, Inflammation - 10061218)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

16) THE PATIENT HAD NOT BEEN USING THE TOILET FOR 8 DAYS, NOT BEEN ABLE TO RELIEVE HIMSELF (Constipation - 10010774, Constipation - 10010774)
Causality as per reporter : Not Reported
Causality as per Mfr : Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) HIGH BLOOD PRESSURE
CORE UnLabeled
2) Stroke, which caused significant sequelae
CORE UnLabeled
3) Heart attack due to Alzheimer's
CORE UnLabeled
4) Heart attack due to Alzheimer's
CORE UnLabeled
5) LOW POTASSIUM
CORE UnLabeled
6) CHEST PNEUMONIA
CORE UnLabeled
7) HE WAS ALMOST DYING
CORE UnLabeled
8) UNABLE TO WALK

Continuation Sheet for CIOMS report

CORE UnLabeled
9) PATIENT COULD NOT BREATHE
CORE UnLabeled
10) bedridden for three years
CORE UnLabeled
11) URINARY INFECTION
CORE Labeled
12) SPENT THE WHOLE NIGHT COMPLAINING (EVERYTHING HURT)
CORE Labeled
13) THE PRESSURE WAS VERY LOW
CORE Labeled
14) IT FEELS VERY BITTER
CORE UnLabeled
15) IT WAS INFLAMMATION BECAUSE THE PATIENT WAS IN BAD SHAPE
CORE UnLabeled
16) THE PATIENT HAD NOT BEEN USING THE TOILET FOR 8 DAYS, NOT BEEN ABLE TO RELIEVE HIMSELF
CORE Labeled

2) Drug : Eligard (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) HIGH BLOOD PRESSURE (Blood pressure high - 10005747, Hypertension - 10020772)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
2) Stroke, which caused significant sequelae (Stroke - 10042244, Cerebrovascular accident - 10008190)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
3) Heart attack due to Alzheimer's (Heart attack - 10019250, Myocardial infarction - 10028596)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
4) Heart attack due to Alzheimer's (Progression of Alzheimer's disease - 10066571, Dementia Alzheimer's type - 10012271)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
5) LOW POTASSIUM (Potassium decreased - 10036443, Blood potassium decreased - 10005724)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
6) CHEST PNEUMONIA (Pneumonia - 10035664, Pneumonia - 10035664)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
7) HE WAS ALMOST DYING (Terminal state - 10048669, Terminal state - 10048669)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
8) UNABLE TO WALK (Unable to walk - 10049278, Gait inability - 10017581)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
9) PATIENT COULD NOT BREATHE (Breathing difficult - 10006338, Dyspnoea - 10013968)

Continuation Sheet for CIOMS report

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

10) bedridden for three years (Bedridden - 10048948, Bedridden - 10048948)
Causality as per reporter : Not Reported

11) URINARY INFECTION (Urinary infection - 10046544, Urinary tract infection - 10046571)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

12) SPENT THE WHOLE NIGHT COMPLAINING (EVERYTHING HURT) (General body pain - 10048971, Pain - 10033371)
Causality as per reporter : Not Reported

13) THE PRESSURE WAS VERY LOW (Blood pressure low - 10005753, Hypotension - 10021097)
Causality as per reporter : Not Reported

14) IT FEELS VERY BITTER (Taste bitter - 10043127, Dysgeusia - 10013911)
Causality as per reporter : Not Reported

15) IT WAS INFLAMMATION BECAUSE THE PATIENT WAS IN BAD SHAPE (Inflammation NOS - 10021961, Inflammation - 10061218)
Causality as per reporter : Not Reported

16) THE PATIENT HAD NOT BEEN USING THE TOILET FOR 8 DAYS, NOT BEEN ABLE TO RELIEVE HIMSELF (Constipation - 10010774, Constipation - 10010774)
Causality as per reporter : Not Reported

Labeling :

1) HIGH BLOOD PRESSURE
CORE
2) Stroke, which caused significant sequelae
CORE
3) Heart attack due to Alzheimer's
CORE
4) Heart attack due to Alzheimer's
CORE
5) LOW POTASSIUM
CORE
6) CHEST PNEUMONIA
CORE
7) HE WAS ALMOST DYING
CORE
8) UNABLE TO WALK
CORE
9) PATIENT COULD NOT BREATHE
CORE
10) bedridden for three years
CORE
11) URINARY INFECTION
CORE
12) SPENT THE WHOLE NIGHT COMPLAINING (EVERYTHING HURT)
CORE
13) THE PRESSURE WAS VERY LOW
CORE
14) IT FEELS VERY BITTER
CORE
15) IT WAS INFLAMMATION BECAUSE THE PATIENT WAS IN BAD SHAPE
CORE
16) THE PATIENT HAD NOT BEEN USING THE TOILET FOR 8 DAYS, NOT BEEN ABLE TO RELIEVE HIMSELF
CORE

3) Drug : Medication for high blood pressure
Active Substance : 1) OTHER THERAPEUTIC PRODUCTS
Drug Characterization : Suspect
Lot Number : 1) Unknown
Indications : 1) High blood pressure [10005747 - Blood pressure high]
Action(s) Taken With Drug : Unknown

Causality

1) HIGH BLOOD PRESSURE (Blood pressure high - 10005747, Hypertension - 10020772)
Causality as per reporter : Not Reported

Continuation Sheet for CIOMS report

2) Stroke, which caused significant sequelae (Stroke - 10042244, Cerebrovascular accident - 10008190)
Causality as per reporter : Not Reported
3) Heart attack due to Alzheimer's (Heart attack - 10019250, Myocardial infarction - 10028596)
Causality as per reporter : Not Reported
4) Heart attack due to Alzheimer's (Progression of Alzheimer's disease - 10066571, Dementia Alzheimer's type - 10012271)
Causality as per reporter : Not Reported
5) LOW POTASSIUM (Potassium decreased - 10036443, Blood potassium decreased - 10005724)
Causality as per reporter : Not Reported
6) CHEST PNEUMONIA (Pneumonia - 10035664, Pneumonia - 10035664)
Causality as per reporter : Not Reported
7) HE WAS ALMOST DYING (Terminal state - 10048669, Terminal state - 10048669)
Causality as per reporter : Not Reported
8) UNABLE TO WALK (Unable to walk - 10049278, Gait inability - 10017581)
Causality as per reporter : Not Reported
9) PATIENT COULD NOT BREATHE (Breathing difficult - 10006338, Dyspnoea - 10013968)
Causality as per reporter : Not Reported
10) bedridden for three years (Bedridden - 10048948, Bedridden - 10048948)
Causality as per reporter : Not Reported
11) URINARY INFECTION (Urinary infection - 10046544, Urinary tract infection - 10046571)
Causality as per reporter : Not Reported
12) SPENT THE WHOLE NIGHT COMPLAINING (EVERYTHING HURT) (General body pain - 10048971, Pain - 10033371)
Causality as per reporter : Not Reported
13) THE PRESSURE WAS VERY LOW (Blood pressure low - 10005753, Hypotension - 10021097)
Causality as per reporter : Not Reported
14) IT FEELS VERY BITTER (Taste bitter - 10043127, Dysgeusia - 10013911)
Causality as per reporter : Not Reported
15) IT WAS INFLAMMATION BECAUSE THE PATIENT WAS IN BAD SHAPE (Inflammation NOS - 10021961, Inflammation - 10061218)
Causality as per reporter : Not Reported
16) THE PATIENT HAD NOT BEEN USING THE TOILET FOR 8 DAYS, NOT BEEN ABLE TO RELIEVE HIMSELF (Constipation - 10010774, Constipation - 10010774)
Causality as per reporter : Not Reported

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

Drug 2 :Eligard® Unspecified Device

1) UNK

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

1). Drug : ANTIBIOTICS
Active Substance : 1) OTHER THERAPEUTIC PRODUCTS
Form Strength :
Indications : 1) Drug use for unknown indication [10057097 - Drug use for unknown indication]

2). Drug : CONCOR
Active Substance : 1) BISOPROLOL FUMARATE
Form Strength :
Route of Admin : 1) Oral
Indications : 1) brain neuron damage [10056389 - Brain damage]

3). Drug : MAGNESIUM
Active Substance : 1) MAGNESIUM
Form Strength :
Route of Admin : 1) Oral
Indications : 1) Drug use for unknown indication [10057097 - Drug use for unknown indication]

Continuation Sheet for CIOMS report

4). Drug	:	ROSUVASTATIN
Active Substance	:	1) ROSUVASTATIN
Form Strength	:	
Route of Admin	:	1) Oral
Indications	:	1) Drug use for unknown indication [10057097 - Drug use for unknown indication]

5). Drug	:	VITAMINS NOS
Active Substance	:	1) VITAMINS NOS
Form Strength	:	
Route of Admin	:	1) Oral
Indications	:	1) drug use for unknown indication [10057097 - Drug use for unknown indication]

6). Drug	:	medication for seizure
Form Strength	:	
Indications	:	1) seizures [10039910 - Seizures]

7). Drug	:	medication for depression
Active Substance	:	1) OTHER THERAPEUTIC PRODUCTS
Form Strength	:	
Indications	:	1) depression [10012378 - Depression]
Dosage Text	:	1) Drug was discontinued

8). Drug	:	medication for anxiety
Active Substance	:	1) OTHER THERAPEUTIC PRODUCTS
Form Strength	:	
Indications	:	1) Anxiety [10002855 - Anxiety]
Dosage Text	:	1) Drug was discontinued

23. OTHER RELEVANT HISTORY (Continuation...)

2) ENEMA ADMINISTRATION (10050314 , Enema administration) (Asked but Unknown -) (Continuing : NO)

3) ALZHEIMER'S DISEASE (10001896 , Alzheimer's disease) (Asked but Unknown -) (Continuing : YES)

4) CONVULSIONS (10010914 , Convulsions) (Asked but Unknown -) (Continuing : Unknown)

5) BLOOD PRESSURE ABNORMAL (10005728 , Blood pressure abnormal) (Continuing : YES)

6) DEPRESSION (10012378 , Depression) (Continuing : Unknown)

7) ANXIETY (10002855 , Anxiety) (Continuing : Unknown)

8) BRAIN NEURON DAMAGE (10056389 , Brain damage) (Continuing : YES)