

SUSPECT ADVERSE REACTION REPORT	
GT-TOLMAR, INC.-22GT036339	

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE Years	3. SEX	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
CSC	GUATEMALA	Day	Month	Year	68	Male	Day	Month	Year	
		14	Oct	1955			10	May	2024	

7+13 DESCRIBE REACTION(S) (including relevant tests/lab data)
 1) X-RAY TO DETERMINE WHERE HE HAD CANCER AND THEY INDICATED THAT HE HAD INFECTION IN THE BONES OF THE SHOULDERS AND IN THE PART OF THE TESTICLES / CANCER HAD SPREAD TO THE BODY AND ARMS, HAD SMALL SPOTS ON HIS BONES AND A LITTLE ON THE SPINE (Metastases to bone (10027452), Metastases to bone (10027452))
 Unknown
 2) FAINTING (Fainting (10016169), Syncope (10042772))
 (10/May/2024 -) - Not Recovered/Not Resolved/Ongoing
 3) Patient has been immobile; has been lying in bed, because he has no movement/Bedridden (Immobile (10021417), Immobile (10021417))
 (12/May/2024 -) - Not Recovered/Not Resolved/Ongoing
 4) BECAUSE OF THE BLISTERS THE PATIENT CAN NO LONGER EAT (Unable to eat (10069830), Feeding disorder (10061148))
 Not Recovered/Not Resolved/Ongoing

Cont..

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, Powder and suspension for suspension for injection)(Unknown)		20. DID EVENT ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA 21. DID EVENT REAPPEAR AFTER REINTRODUCTION <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA (NA : Not Applicable)
15. DAILY DOSE(S) 1) (45 milligram(s), 1 in 6 Month) 2) (45 milligram(s), 1 in 6 Month)		
16. ROUTE(S) OF ADMINISTRATION 1) Subcutaneous 2) Subcutaneous		
Cont..		
17. INDICATION(S) FOR USE 1) Prostate cancer [10060862 - Prostate cancer]		
18. THERAPY DATE(S) (from/to) 1) (/2022 - Ongoing)		19. THERAPY DURATION
Cont..		

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction) 1) TEOPRIN(BICALUTAMIDE)(Capsule)	Cont..
23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergies, pregnancy with last month of period, etc.) 1) PROSTATE CANCER (10060862, Prostate cancer) (Continuing: Yes)	

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER 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 <input type="checkbox"/> YES <input type="checkbox"/> NO	24b. MFR CONTROL NO. GT-TOLMAR, INC.-22GT036339		
24c. DATE RECEIVED BY MANUFACTURER 06/May/2025	24d. REPORT SOURCE <input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL		
DATE OF THIS REPORT 17/May/2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP		

= Continuation attached sheet(s)..

Continuation Sheet for CIOMS report

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

5) FRACTURES ON THE SPINE (Fracture of spine (10017213), Spinal fracture (10041569) - Unknown)

6) INFECTION IN THE BONES OF THE SHOULDERS AND IN THE PART OF THE TESTICLES (Bone infection (10061017), Osteomyelitis (10031252) - Unknown)

7) INFECTION IN THE BONES OF THE SHOULDERS AND IN THE PART OF THE TESTICLES (Testicular infection (10062591), Orchitis (10031064) - Unknown)

8) TONGUE WAS STUCK (Tongue abnormal feeling of (10043934), Paraesthesia oral (10057372)(11/May/2024 -) - Not Recovered/Not Resolved/Ongoing)

9) PATIENT HAD NO MOVEMENT IN HIS TONGUE; PATIENT CANNOT MOVE HIS TONGUE (Tongue movement impaired (10043964), Tongue movement disturbance (10043963)(11/May/2024 -) - Not Recovered/Not Resolved/Ongoing)

10) BLISTERS ON THE BOTTOM AND TOP OF THE TONGUE (Tongue blistering (10043942), Tongue blistering (10043942)(11/May/2024 -) - Not Recovered/Not Resolved/Ongoing)

11) IT WAS AS IF HIS TONGUE HAD BEEN BURNT BECAUSE IT WAS PURPLE (Tongue discolouration (10043949), Tongue discolouration (10043949)(11/May/2024 -) - Not Recovered/Not Resolved/Ongoing)

12) PATIENT'S MOUTH WAS BLEEDING (Bleeding mouth (10049331), Mouth haemorrhage (10028024)(11/May/2024 -) - Not Recovered/Not Resolved/Ongoing)

13) PATIENT'S MOUTH FELT DRY (Dry mouth (10013781), Dry mouth (10013781)(11/May/2024 -) - Not Recovered/Not Resolved/Ongoing)

14) BLISTERS APPEARED ALL OVER THE PATIENT'S MOUTH (Blistering of mouth (10005215), Oral mucosal blistering (10030995)(15/May/2024 -) - Not Recovered/Not Resolved/Ongoing)

15) PATIENT CANNOT SPEAK (Speech disorder (10041466), Speech disorder (10041466) - Not Recovered/Not Resolved/Ongoing)

16) Blisters in stomach and intestine (Gastrointestinal disorder (10017944), Gastrointestinal disorder (10017944) - Not Recovered/Not Resolved/Ongoing)

17) weakness (Weakness (10047862), Asthenia (10003549) - Not Recovered/Not Resolved/Ongoing)

18) vomiting (Vomiting (10047700), Vomiting (10047700) - Not Recovered/Not Resolved/Ongoing)

Event Description :

This Study report from GUATEMALA was received by Adium (Mfr No.: GT-0905-20220826) on 25-AUG-2022 from two Consumers regarding a 66 Years old Male patient who experienced the medically significant and life threatening event of X-ray to determine where he had cancer and they indicated that he had infection in the bones of the shoulders and in the part of the testicles / Cancer had spread to the body and arms, had small spots on his bones and a little on the spine (Metastases to bone), and the medically significant events of Infection in the bones of the shoulders and in the part of the testicles (Bone infection, Testicular infection), Fractures on the spine (Fracture of spine), during Eligard (Leuprolide acetate) 45 milligram therapy for Prostate cancer. The needle component of the constituent device was not identified in the report. The report was sent to Tolmar on 26-AUG-2022.

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

Concomitant medications were not reported.

Since Apr 2022 or May 2022, the patient began receiving Eligard 45 milligram, q 6 month, via Subcutaneous use for Prostate cancer (Batch details not provided). On an unspecified date, the patient's shoulder bones hurt and had an x-ray to determine where he had cancer and they indicated that he had infection in the bones of the shoulders and in the part of the testicles. Additionally, it was reported that the x-ray was performed because the patient was suffering from pain in the spine, he was told that the results showed that the patient had fractures in the spine and after a month or two months (exact date not provided) he was sent for an x-ray. According to the results, the doctor indicated that it was already cancer and that it had spread to the body and arms, telling him that he already had small spots on his bones and a little on the spine. Patient was prescribed a pain medication, 1 capsule per day for 30 days (drug details not provided as reporter was not at home). The next application of ELIGARD would be approximately in November. Patient would have an appointment on September 18, 2022 to verify how was he doing. Corrective treatment included Pain medication. Action taken with Eligard in response to the events was Dose Not Changed. De-challenge and re-challenge were not applicable. The outcome of Metastases to bone was Unknown. The outcome of Bone infection was Unknown. The outcome of Testicular infection was Unknown. The outcome of Fracture of spine was Unknown.

Continuation Sheet for CIOMS report

Relevant test results included:

X-ray (unknown date)

X-ray (unknown date)

The reporter assessed the seriousness of Metastases to bone as life threatening, did not assess the seriousness of the remaining events and did not assess causality in relationship to Eligard therapy.

On 17-MAY-2024, follow-up information was received by Adium via Patient Support Program (reference number: GT-0905-20220826) from a Consumer and sent to Tolmar on 20-MAY-2024. New information included: added concomitant medications, added new medically important events of Because of the blisters the patient can no longer eat (Unable to eat), Fainting (Fainting) and Patient has been immobile; has been lying in bed, because he has no movement (Immobile) and non-serious events of Tongue was stuck (Tongue abnormal feeling of), Patient had no movement in his tongue; patient cannot move his tongue (Tongue movement impaired), Blisters on the bottom and top of the tongue (Tongue blistering), It was as if his tongue had been burnt because it was purple (Tongue discolouration), Blisters appeared all over the patient's mouth (Blistering of mouth), Patient's mouth was bleeding (Bleeding mouth), Patient cannot speak (Speech disorder) and Patient's mouth felt dry (Dry mouth).

Concomitant medications included, TEOPRIN, CHEMOTHERAPY, FILGRASTIM.

On 10-MAY-2024, the patient underwent chemotherapy, but reporter was not sure, because they sent the patient to the basement to be given a serum, and then they sent him the FILGRASTIM drug, to be applied to the patient every 2 days. The reporter mentioned that on the same day that the patient was taken home the patient was fainting. On 11-MAY-2024 when the patient woke up his tongue was stuck (it was not specified where), the patient could not move it anywhere, he had no movement in his tongue and it was as if his tongue had been burnt because it was purple. According to the reporter, the patient was given FILGRASTIM as chemotherapy, prescribed by the hospital, on 12-MAY-2024 and on 14-MAY-2024. Since 12-MAY-2024 and 13-MAY-2024, patient had been immobile, patient had been lying in bed, because he had no movement as if the patient was already dying, because reporter only listened to his heartbeat. On 15-MAY-2024, relatives noticed that blisters appeared all over the patient's mouth, on the bottom and top of the tongue, the patient's mouth felt dry and was bleeding, as if the patient had drunk hot water. The reporter assumed that the chemotherapy patient received burned the patient's mouth and caused the blisters and because of the blisters the patient could no longer eat, speak and could not move his tongue. They had not consulted with the oncology doctor about these symptoms, because next appointment would be on 31-MAY-2024. TEOPRIN, was received as maintenance and patient had been taking it since he started the Eligard treatment about 2 years ago, reporter did not refer to the date, only that the patient had been taking the drug Eligard for 5 or 6 applications, he did not have an expiry date and batch numbers. 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 Unable to eat was Not Recovered/Not Resolved. The outcome of Fainting was Not Recovered/Not Resolved. The outcome of Tongue abnormal feeling of was Not Recovered/Not Resolved. The outcome of Tongue movement impaired was Not Recovered/Not Resolved. The outcome of Tongue blistering was Not Recovered/Not Resolved. The outcome of Tongue discolouration was Not Recovered/Not Resolved. The outcome of Blistering of mouth was Not Recovered/Not Resolved. The outcome of Immobile was Not Recovered/Not Resolved. The outcome of Bleeding mouth was Not Recovered/Not Resolved. The outcome of Speech disorder was Not Recovered/Not Resolved. The outcome of Dry mouth was Not Recovered/Not Resolved.

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

On 19-SEP-2024, upon internal review, the event of Immobile was upgraded to serious (Medically significant) as per important medical events list. No further changes were performed.

On 06-May-2025, follow up information was received via by Adium ((reference number: (GT-0905-20220826). New information included: New non-serious event of 'weakness' (asthenia), 'vomiting' (vomiting), Blisters in stomach and intestine' (gastrointestinal disorder). The verbatim of event (Immobile) updated from 'Patient has been immobile; has been lying in bed, because he has no movement' to 'Patient has been immobile; has been lying in bed, because he has no movement/Bedridden' New Eligard dose details were added. Treatment drug details were added.

On 20-Nov-2024, the patient received last dose of Eligard 45 mg, every 6 months via subcutaneous route for prostate cancer (lot numbers and expiration dates were not provided) and his next dose was due for 14-May-2025.

On an unknown date, the patient's son mentions that the patient had been in bad shape for month as he cannot walk or get up, didn't eat as when he eats he vomits and he didn't know what happened to patient after second chemotherapy and since the patient fell once in bed he commented that the patient was due for his chemotherapy and was instructed to pause the treatment as he was very weak. Additionally, the patient son commented that the chemotherapy was affecting his intestine and stomach as he got blisters in intestine and stomach and the patient's private doctor suggested to have a test on his kidneys and liver to check whether the cancer had affected to these parts. The patient's son noted that the patient's health was getting worse every day.

On 16-Jun-2025, the patient had an appointment to have chest and full abdominal exams.

Corrective treatment included Enantyum plus 5mg /25 ml, Monilac syrup 10mg/ 15 ml and Esogastric 40mg for pain (spinal pain due to spinal fracture).

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 asthenia, vomiting and gastrointestinal disorder was not resolved.

The reporter did not assess the seriousness of event asthenia, vomiting and gastrointestinal disorder.

Continuation Sheet for CIOMS report

The reporter did not provide the causality for asthenia, vomiting and gastrointestinal disorder in relation to Eligard and Eligard Unspecified Device.

Note: Event pain (reported in context of pain in spine which on X-ray was confirmed pain due to fractures in the spine) In follow up version was already reported in the initial version hence, it was not coded in the follow up version. However, the event spinal fracture was coded in the initial version. The treatment drugs reported for the event pain were mentioned in the follow up narrative.

Listedness of previously reported events retained as per previous assessment.

Gastrointestinal disorder>Eligard>Unlisted as per CCDS>07-Nov-2024

Gastrointestinal disorder>Eligard>Unlisted as per USPI>Feb-2025

Gastrointestinal disorder>Eligard unspecified device>Unlisted as per USPI>Feb-2025

Gastrointestinal disorder>Eligard>Unlisted as per Canadian monograph>02-Apr-2025

Asthenia>Eligard>listed as per CCDS>07-Nov-2024

Asthenia>Eligard>listed as per USPI>Feb-2025

Asthenia>Eligard unspecified device>listed as per USPI>Feb-2025

Asthenia>Eligard>listed as per Canadian monograph>02-Apr-2025

Vomiting>Eligard>listed as per CCDS>07-Nov-2024

Vomiting>Eligard>listed as per USPI>Feb-2025

Vomiting>Eligard unspecified device>listed as per USPI>Feb-2025

Vomiting>Eligard>listed as per Canadian monograph>02-Apr-2025

Company Remarks (Sender's Comments) :

Evaluator Comment (Tolmar): This 66 year old male patient experienced metastases to bone (X-ray to determine where he had cancer and they indicated that he had infection in the bones of the shoulders and in the part of the testicles/Cancer had spread to the body and arms, had small spots on his bones and a little on the spine), osteomyelitis and orchitis (Infection in the bones of the shoulders and in the part of the testicles), spinal fracture (Fractures on the spine) during Eligard (Leuprolide acetate) 45 mg therapy for prostate cancer. Metastases to bone was assessed as serious due to threat to life and its clinical significance, bone infection, testicular infection and fracture of spine were assessed as serious due to their clinical significance, considering the impact on patient's health. Metastases to bone was a natural course of underlying malignancy. Fracture of spine was likely due to Metastases to bone. Bone infection and Testicular infection were likely facilitated by low immunity due to underlying malignancy. Hence, events are assessed as not related to leuprolide (drug and device).

As per the follow up information provided patient experienced syncope (Fainting), dry mouth (Patient's mouth felt dry), mouth haemorrhage (Patient's mouth was bleeding), immobile (Patient has been immobile; has been lying in bed, because he has no movement), oral mucosal blistering (Blisters appeared all over the patient's mouth), tongue discoloration (It was as if his tongue had been burnt because it was purple), tongue blistering (Blisters on the bottom and top of the tongue), tongue movement disturbance (Patient had no movement in his tongue; patient cannot move his tongue), feeding disorder (Because of the blisters the patient can no longer eat), speech disorder (Patient cannot speak) and paraesthesia oral (tongue was stuck). Tolmar assessed the events feeding disorder, immobile and syncope as serious (MS) based on the clinical relevance and significant impact on patient's health, while all other events are considered as non-serious as there is no immediate jeopardy noted and they did not meet ICH seriousness criteria. All the events are considered as not related to Eligard (drug and device). Events dry mouth, tongue blistering, oral mucosal blistering, tongue movement disturbance, tongue discoloration, tongue movement disturbance, mouth haemorrhage and paraesthesia oral are attributable to the co-suspect chemotherapy. Syncope is not attributable to the Eligard, based on the case context it is attributable to co-suspect. Elderly age and underlying prostate cancer are strong confounders. Events feeding disorder and speech disorder are due to oral mucosal blistering and tongue blistering. Immobile is due to elderly age and impact of the associated serious adverse events. Elderly age is a risk factor for immobile.

FU added events of gastrointestinal disorder (Blisters in stomach and intestine), vomiting (Vomiting) and asthenia (Weakness). Tolmar assessed reported events as non-serious since they did not meet the ICH seriousness criteria and are not IME events. The reported events were assessed as not related to Eligard (drug and device) as the event gastrointestinal disorder can be explained due to cosuspect chemotherapy considering close temporality. Asthenia and vomiting are attributable to cosuspect chemotherapy and underlying prostate cancer.

Additional Information (Continuation...)

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

1) Test Name: X-RAY

Result Unstructured Data (free text) : To determine where he had cancer and they indicated that he had infection in the bones of the shoulders and in the part of the testicles. Cancer had spread to the body and arms, telling him that he already had small spots on his bones and a little on the spine

Test Date:

2) Test Name: X-RAY

Result Unstructured Data (free text) : Fractures in the spine

Test Date:

Lab Comments :

1) Test Name : X-RAY

Lab Comments : To determine where he had cancer and they indicated that he had infection in the bones of the shoulders and in the part of the testicles. Cancer had spread to the body and arms, telling him that he already had small spots on his bones and a little on the spine

2) Test Name : X-RAY

Lab Comments : Fractures in the spine

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) Powder and suspension for suspension for injection
Lot Number	: 1) Unknown 2) 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 : //2022 To :Continuing 2) From : 20/Nov/2024 To :Continuing
Action(s) Taken With Drug	: Dose not changed

Causality

1) X-RAY TO DETERMINE WHERE HE HAD CANCER AND THEY INDICATED THAT HE HAD INFECTION IN THE BONES OF THE SHOULDERS AND IN THE PART OF THE TESTICLES / CANCER HAD SPREAD TO THE BODY AND ARMS, HAD SMALL SPOTS ON HIS BONES AND A LITTLE ON THE SPINE (Metastases to bone - 10027452, Metastases to bone - 10027452)

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

2) FAINTING (Fainting - 10016169, Syncope - 10042772)

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

3) Patient has been immobile; has been lying in bed, because he has no movement/Bedridden (Immobile - 10021417, Immobile - 10021417)

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

4) BECAUSE OF THE BLISTERS THE PATIENT CAN NO LONGER EAT (Unable to eat - 10069830, Feeding disorder - 10061148)

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

5) FRACTURES ON THE SPINE (Fracture of spine - 10017213, Spinal fracture - 10041569)

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

6) INFECTION IN THE BONES OF THE SHOULDERS AND IN THE PART OF THE TESTICLES (Bone infection - 10061017, Osteomyelitis - 10031252)

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

7) INFECTION IN THE BONES OF THE SHOULDERS AND IN THE PART OF THE TESTICLES (Testicular infection - 10062591, Orchitis - 10031064)

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

8) TONGUE WAS STUCK (Tonque abnormal feeling of - 10043934, Paraesthesia oral - 10057372)

Continuation Sheet for CIOMS report

- Causality as per reporter : Not Reported
 Causality as per Mfr : Not Related
 DeChallenge : Not applicable
 ReChallenge : Not Applicable
- 9) PATIENT HAD NO MOVEMENT IN HIS TONGUE; PATIENT CANNOT MOVE HIS TONGUE (Tongue movement impaired - 10043964, Tongue movement disturbance - 10043963)
 Causality as per reporter : Not Reported
 Causality as per Mfr : Not Related
 DeChallenge : Not applicable
 ReChallenge : Not Applicable
- 10) BLISTERS ON THE BOTTOM AND TOP OF THE TONGUE (Tongue blistering - 10043942, Tongue blistering - 10043942)
 Causality as per reporter : Not Reported
 Causality as per Mfr : Not Related
 DeChallenge : Not applicable
 ReChallenge : Not Applicable
- 11) IT WAS AS IF HIS TONGUE HAD BEEN BURNT BECAUSE IT WAS PURPLE (Tongue discolouration - 10043949, Tongue discolouration - 10043949)
 Causality as per reporter : Not Reported
 Causality as per Mfr : Not Related
 DeChallenge : Not applicable
 ReChallenge : Not Applicable
- 12) PATIENT'S MOUTH WAS BLEEDING (Bleeding mouth - 10049331, Mouth haemorrhage - 10028024)
 Causality as per reporter : Not Reported
 Causality as per Mfr : Not Related
 DeChallenge : Not applicable
 ReChallenge : Not Applicable
- 13) PATIENT'S MOUTH FELT DRY (Dry mouth - 10013781, Dry mouth - 10013781)
 Causality as per reporter : Not Reported
 Causality as per Mfr : Not Related
 DeChallenge : Not applicable
 ReChallenge : Not Applicable
- 14) BLISTERS APPEARED ALL OVER THE PATIENT'S MOUTH (Blistering of mouth - 10005215, Oral mucosal blistering - 10030995)
 Causality as per reporter : Not Reported
 Causality as per Mfr : Not Related
 DeChallenge : Not applicable
 ReChallenge : Not Applicable
- 15) PATIENT CANNOT SPEAK (Speech disorder - 10041466, Speech disorder - 10041466)
 Causality as per reporter : Not Reported
 Causality as per Mfr : Not Related
 DeChallenge : Not applicable
 ReChallenge : Not Applicable
- 16) Blisters in stomach and intestine (Gastrointestinal disorder - 10017944, Gastrointestinal disorder - 10017944)
 Causality as per reporter : Not Reported
 Causality as per Mfr : Not Related
 DeChallenge : Not applicable
 ReChallenge : Not Applicable
- 17) weakness (Weakness - 10047862, Asthenia - 10003549)
 Causality as per reporter : Not Reported
 Causality as per Mfr : Not Related
 DeChallenge : Not applicable
 ReChallenge : Not Applicable
- 18) vomiting (Vomiting - 10047700, Vomiting - 10047700)
 Causality as per reporter : Not Reported
 Causality as per Mfr : Not Related
 DeChallenge : Not applicable
 ReChallenge : Not Applicable

Labeling :

- 1) X-RAY TO DETERMINE WHERE HE HAD CANCER AND THEY INDICATED THAT HE HAD INFECTION IN THE BONES OF THE SHOULDERS AND IN THE PART OF THE TESTICLES / CANCER HAD SPREAD TO THE BODY AND ARMS, HAD SMALL SPOTS ON HIS BONES AND A LITTLE ON THE SPINE
 CORE Labeled
- 2) FAINTING
 CORE Labeled
- 3) Patient has been immobile; has been lying in bed, because he has no movement/Bedridden
 CORE UnLabeled

Continuation Sheet for CIOMS report

- 4) BECAUSE OF THE BLISTERS THE PATIENT CAN NO LONGER EAT
CORE UnLabeled
- 5) FRACTURES ON THE SPINE
CORE UnLabeled
- 6) INFECTION IN THE BONES OF THE SHOULDERS AND IN THE PART OF THE TESTICLES
CORE UnLabeled
- 7) INFECTION IN THE BONES OF THE SHOULDERS AND IN THE PART OF THE TESTICLES
CORE UnLabeled
- 8) TONGUE WAS STUCK
CORE UnLabeled
- 9) PATIENT HAD NO MOVEMENT IN HIS TONGUE; PATIENT CANNOT MOVE HIS TONGUE
CORE UnLabeled
- 10) BLISTERS ON THE BOTTOM AND TOP OF THE TONGUE
CORE UnLabeled
- 11) IT WAS AS IF HIS TONGUE HAD BEEN BURNT BECAUSE IT WAS PURPLE
CORE UnLabeled
- 12) PATIENT'S MOUTH WAS BLEEDING
CORE UnLabeled
- 13) PATIENT'S MOUTH FELT DRY
CORE Labeled
- 14) BLISTERS APPEARED ALL OVER THE PATIENT'S MOUTH
CORE UnLabeled
- 15) PATIENT CANNOT SPEAK
CORE UnLabeled
- 16) Blisters in stomach and intestine
CORE UnLabeled
- 17) weakness
CORE Labeled
- 18) vomiting
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) Other
Indications : 1) prostate cancer [10060862 - Prostate cancer]
Action(s) Taken With Drug : Not applicable

Causality

- 1) X-RAY TO DETERMINE WHERE HE HAD CANCER AND THEY INDICATED THAT HE HAD INFECTION IN THE BONES OF THE SHOULDERS AND IN THE PART OF THE TESTICLES / CANCER HAD SPREAD TO THE BODY AND ARMS, HAD SMALL SPOTS ON HIS BONES AND A LITTLE ON THE SPINE (Metastases to bone - 10027452, Metastases to bone - 10027452)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
- 2) FAINTING (Fainting - 10016169, Syncope - 10042772)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
- 3) Patient has been immobile; has been lying in bed, because he has no movement/Bedridden (Immobile - 10021417, Immobile - 10021417)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
- 4) BECAUSE OF THE BLISTERS THE PATIENT CAN NO LONGER EAT (Unable to eat - 10069830, Feeding disorder - 10061148)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
- 5) FRACTURES ON THE SPINE (Fracture of spine - 10017213, Spinal fracture - 10041569)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable

Continuation Sheet for CIOMS report

- ReChallenge : Not Applicable
- 6) INFECTION IN THE BONES OF THE SHOULDERS AND IN THE PART OF THE TESTICLES (Bone infection - 10061017, Osteomyelitis - 10031252)
- Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
- 7) INFECTION IN THE BONES OF THE SHOULDERS AND IN THE PART OF THE TESTICLES (Testicular infection - 10062591, Orchitis - 10031064)
- Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
- 8) TONGUE WAS STUCK (Tongue abnormal feeling of - 10043934, Paraesthesia oral - 10057372)
- Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
- 9) PATIENT HAD NO MOVEMENT IN HIS TONGUE; PATIENT CANNOT MOVE HIS TONGUE (Tongue movement impaired - 10043964, Tongue movement disturbance - 10043963)
- Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
- 10) BLISTERS ON THE BOTTOM AND TOP OF THE TONGUE (Tongue blistering - 10043942, Tongue blistering - 10043942)
- Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
- 11) IT WAS AS IF HIS TONGUE HAD BEEN BURNT BECAUSE IT WAS PURPLE (Tongue discolouration - 10043949, Tongue discolouration - 10043949)
- Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
- 12) PATIENT'S MOUTH WAS BLEEDING (Bleeding mouth - 10049331, Mouth haemorrhage - 10028024)
- Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
- 13) PATIENT'S MOUTH FELT DRY (Dry mouth - 10013781, Dry mouth - 10013781)
- Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
- 14) BLISTERS APPEARED ALL OVER THE PATIENT'S MOUTH (Blistering of mouth - 10005215, Oral mucosal blistering - 10030995)
- Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
- 15) PATIENT CANNOT SPEAK (Speech disorder - 10041466, Speech disorder - 10041466)
- Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
- 16) Blisters in stomach and intestine (Gastrointestinal disorder - 10017944, Gastrointestinal disorder - 10017944)
- Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
- 17) weakness (Weakness - 10047862, Asthenia - 10003549)
- Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
- 18) vomiting (Vomiting - 10047700, Vomiting - 10047700)
- Causality as per reporter : Not Reported

Continuation Sheet for CIOMS report

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

Labeling :

- 1) X-RAY TO DETERMINE WHERE HE HAD CANCER AND THEY INDICATED THAT HE HAD INFECTION IN THE BONES OF THE SHOULDERS AND IN THE PART OF THE TESTICLES / CANCER HAD SPREAD TO THE BODY AND ARMS, HAD SMALL SPOTS ON HIS BONES AND A LITTLE ON THE SPINE
CORE
- 2) FAINTING
CORE
- 3) Patient has been immobile; has been lying in bed, because he has no movement/Bedridden
CORE
- 4) BECAUSE OF THE BLISTERS THE PATIENT CAN NO LONGER EAT
CORE
- 5) FRACTURES ON THE SPINE
CORE
- 6) INFECTION IN THE BONES OF THE SHOULDERS AND IN THE PART OF THE TESTICLES
CORE
- 7) INFECTION IN THE BONES OF THE SHOULDERS AND IN THE PART OF THE TESTICLES
CORE
- 8) TONGUE WAS STUCK
CORE
- 9) PATIENT HAD NO MOVEMENT IN HIS TONGUE; PATIENT CANNOT MOVE HIS TONGUE
CORE
- 10) BLISTERS ON THE BOTTOM AND TOP OF THE TONGUE
CORE
- 11) IT WAS AS IF HIS TONGUE HAD BEEN BURNT BECAUSE IT WAS PURPLE
CORE
- 12) PATIENT'S MOUTH WAS BLEEDING
CORE
- 13) PATIENT'S MOUTH FELT DRY
CORE
- 14) BLISTERS APPEARED ALL OVER THE PATIENT'S MOUTH
CORE
- 15) PATIENT CANNOT SPEAK
CORE
- 16) Blisters in stomach and intestine
CORE
- 17) weakness
CORE
- 18) vomiting
CORE
- 3) Drug : Chemotherapy
 Active Substance : 1) OTHER THERAPEUTIC PRODUCTS
 Drug Characterization : Suspect
 Indications : 1) Product used for unknown indication [10070592 - Product used for unknown indication]
 Therapy Dates : 1) From : 10/May/2024 To :Unknown
 Action(s) Taken With Drug : Unknown

Causality

- 1) X-RAY TO DETERMINE WHERE HE HAD CANCER AND THEY INDICATED THAT HE HAD INFECTION IN THE BONES OF THE SHOULDERS AND IN THE PART OF THE TESTICLES / CANCER HAD SPREAD TO THE BODY AND ARMS, HAD SMALL SPOTS ON HIS BONES AND A LITTLE ON THE SPINE (Metastases to bone - 10027452, Metastases to bone - 10027452)
Causality as per reporter : Not Reported
- 2) FAINTING (Fainting - 10016169, Syncope - 10042772)
Causality as per reporter : Not Reported
- 3) Patient has been immobile; has been lying in bed, because he has no movement/Bedridden (Immobile - 10021417, Immobile - 10021417)
Causality as per reporter : Not Reported
- 4) BECAUSE OF THE BLISTERS THE PATIENT CAN NO LONGER EAT (Unable to eat - 10069830, Feeding disorder - 10061148)
Causality as per reporter : Not Reported
- 5) FRACTURES ON THE SPINE (Fracture of spine - 10017213, Spinal fracture - 10041569)
Causality as per reporter : Not Reported
- 6) INFECTION IN THE BONES OF THE SHOULDERS AND IN THE PART OF THE TESTICLES (Bone infection - 10061017, Osteomyelitis - 10031252)
Causality as per reporter : Not Reported

Continuation Sheet for CIOMS report

- 7) INFECTION IN THE BONES OF THE SHOULDERS AND IN THE PART OF THE TESTICLES (Testicular infection - 10062591, Orchitis - 10031064)
Causality as per reporter : Not Reported
- 8) TONGUE WAS STUCK (Tongue abnormal feeling of - 10043934, Paraesthesia oral - 10057372)
Causality as per reporter : Not Reported
- 9) PATIENT HAD NO MOVEMENT IN HIS TONGUE; PATIENT CANNOT MOVE HIS TONGUE (Tongue movement impaired - 10043964, Tongue movement disturbance - 10043963)
Causality as per reporter : Not Reported
- 10) BLISTERS ON THE BOTTOM AND TOP OF THE TONGUE (Tongue blistering - 10043942, Tongue blistering - 10043942)
Causality as per reporter : Not Reported
- 11) IT WAS AS IF HIS TONGUE HAD BEEN BURNT BECAUSE IT WAS PURPLE (Tongue discolouration - 10043949, Tongue discolouration - 10043949)
Causality as per reporter : Not Reported
DeChallenge : Not applicable
ReChallenge : Not Applicable
- 12) PATIENT'S MOUTH WAS BLEEDING (Bleeding mouth - 10049331, Mouth haemorrhage - 10028024)
Causality as per reporter : Not Reported
DeChallenge : Not applicable
ReChallenge : Not Applicable
- 13) PATIENT'S MOUTH FELT DRY (Dry mouth - 10013781, Dry mouth - 10013781)
Causality as per reporter : Not Reported
DeChallenge : Not applicable
ReChallenge : Not Applicable
- 14) BLISTERS APPEARED ALL OVER THE PATIENT'S MOUTH (Blistering of mouth - 10005215, Oral mucosal blistering - 10030995)
Causality as per reporter : Not Reported
DeChallenge : Not applicable
ReChallenge : Not Applicable
- 15) PATIENT CANNOT SPEAK (Speech disorder - 10041466, Speech disorder - 10041466)
Causality as per reporter : Not Reported
DeChallenge : Not applicable
ReChallenge : Not Applicable
- 16) Blisters in stomach and intestine (Gastrointestinal disorder - 10017944, Gastrointestinal disorder - 10017944)
Causality as per reporter : Not Reported
DeChallenge : Not applicable
ReChallenge : Not Applicable
- 17) weakness (Weakness - 10047862, Asthenia - 10003549)
Causality as per reporter : Not Reported
DeChallenge : Not applicable
ReChallenge : Not Applicable
- 18) vomiting (Vomiting - 10047700, Vomiting - 10047700)
Causality as per reporter : Not Reported
DeChallenge : Not applicable
ReChallenge : Not Applicable

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

Dosage Text :

Drug 1 :Eligard®

1) 45 milligram, q 6 month

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

1). Drug	:	TEOPRIN
Active Substance	:	1) BICALUTAMIDE
Form Strength	:	
Form of Admin	:	1) Capsule
Daily Dose	:	
Indications	:	1) Product used for unknown indication [10070592 - Product used for unknown indication]
Dosage Text	:	1) 1 dosage form

2). Drug	:	FILGRASTIM
Active Substance	:	1) FILGRASTIM
Form Strength	:	
Daily Dose	:	1) (300 milligram(s))
Indications	:	1) Product used for unknown indication [10070592 - Product used for unknown indication]

Continuation Sheet for CIOMS report

Therapy Dates	:	1) From : 12/May/2024 To :
		2) From : 14/May/2024 To :
		3) From : 28/Mar/2025 To :
Dosage Text	:	1) 300mg/ml
3). Drug	:	Pain medication
Active Substance	:	1) OTHER THERAPEUTIC PRODUCTS
Form Strength	:	
Indications	:	1) Pain [10033371 - Pain]