CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

2022US030843

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
Masked	PANAMA	Masked	Masked	Masked	82	Male		Jun	2022

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

1) Unable to eat (Unable to eat (10069830), Feeding disorder (10061148))
(//2023 -) - Not Recovered/Not Resolved/Ongoing
2) generalized deterioration (General physical health deterioration (10049438), General physical health deterioration (10049438))
(/May/2025 -) - Not Recovered/Not Resolved/Ongoing
3) Patient can no longer eat things (solids) because otherwise he chokes (Choked on food (10008588), Choking (10008589))
(//2023 -) - Unknown
4) Heart murmur (Heart murmur (10019295), Cardiac murmur (10007586))
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) Enzalutamide (Enzalutamide, Enzalutamide) (Suspect) (Verum) (40 Milligram, Capsule)(L1881288AJ)(40 Milligram, Capsule)(L1881288AJ)

Cont..

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

15. DAILY DOSE(S)

1) 160.0 milligram(s) (160 milligram(s), 1 in 1 Day)

(80 milligram(s))

16. ROUTE(S) OF ADMINISTRATION

1) Oral
2) Oral

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

(NA : Not Applicable)

17. INDICATION(S) FOR USE

1) Prostate cancer [10060862 - Prostate cancer]

18. THERAPY DATE(S) (from/to)	19. THERAPY DURATION
1) (28/Jan/2019 -)	

III. CONCOMITANT DRUG(S) AND HISTORY

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

1)Aprovel(IRBESARTAN)(300 Milligram, Capsule)

Cont..

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

1) THROMBOSIS IN THE LEGS (10043623, Thrombosis leg) (//2015 -) (Continuing: Yes)

Cont..

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER

Name : Astellas Pharma Global Development, Inc.
2375 Waterview Drive
Northbrook, IL, 60062-6111, UNITED STATES OF AMERICA

Study Information
Study Name: Enzalutamide Patient Support Progr (Cont..)
EudraCT Number:
Protocol No.: Enzalutamide_Astellas PSP
Center No.:
Subject Id :

24.REPORT NULLIFIED	24b. MFR CONTROL NO.
☐ YES ☐ NO	2022US030843
24c. DATE RECEIVED BY MANUFACTURER	24d. REPORT SOURCE
05/Jun/2025	☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT	25a. REPORT TYPE
09/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) There are days when he is well and others when he is not and his disease (Alzheimer's disease) makes him altered (Feeling abnormal (10016322), Feeling abnormal (10016322)(Asked but Unknown -) - Unknown)

6) had a heart problem (Heart disorder (10019277), Cardiac disorder (10061024)(//2024 -) - Unknown)

7) thyroid problems (Thyroid disorder (10043709), Thyroid disorder (10043709) - Not Recovered/Not Resolved/Ongoing)

8) Applications of Eligard for the patient were painful (Injection site pain (10022086), Injection site pain (10022086) - Unknown)

9) It was impossible for him to take all 4 at the same time/difficult for him to ingest the therapy (Product difficult to swallow (10075696), Product use complaint (10079400) - Unknown)

10) Wife cuts soft Xtandi capsules to give to patient in straw/ doctor was the one who gave the order for the patient to take them in this way (Wrong technique in product usage process (10076573), Wrong technique in product usage process (10076573) - Unknown)

11) Wife cuts soft Xtandi capsules to give to patient in straw/ doctor was the one who gave the order for the patient to take them in this way (Off label use (10053762), Off label use (10053762) - Unknown)

12) Patient received 2 capsules in the morning and during the course of the day the other two so that he can take all 4 capsules (Inappropriate schedule of drug administration (10021597), Inappropriate schedule of product administration (10081572)(/Jun/2022 -) - Unknown)

Event Description :

Information was received by Astellas business partner Asofarma (a subsidiary of Tecnofarma S. A) from a Consumer (patient's wife) in PANAMA on 26-Aug-2022, and was received at Astellas from Asofarma (Reference number: PA-0079-20220827) on 27-Aug-2022 concerning an 82 Year(s) old Male patient, enrolled in post-marketing study: Enzalutamide Patient Support Program who was on Xtandi (enzalutamide), Capsule (160 milligram(s), 1 every 1 Day). Indication for use was Prostate cancer. The lot number was L1881288AJ. The patient-initiated treatment on 28-Jan-2019.

Study no: Enzalutamide_Astellas PSP: Open label study.

The patient received enzalutamide for prostate cancer according to the following dosage regimens: 28-Jan-2019 (however also reported as 24-Jan-2019) - (stop date not provided): Oral 160 mg, once daily and Jun-2022 - (ongoing): Oral 80 mg, 2 capsules in the morning and during the day the other two.

The patient also received other suspect drug Eligard (leuprorelin acetate) for prostate cancer according to the following dosage regimen: 09-Mar-2023 - 2024: subcutaneous, unknown dose and frequency.

Action taken with the enzalutamide treatment in response to the event it was impossible to take all 4 at the same time/difficult for him to ingest the therapy was drug withdrawn (reported as suspended) and in response to other events was no change.

Action taken with leuprorelin acetate in response to the event Applications of Eligard for the patient were painful was withdrawn and response to other events was unknown.

Patient's wife mentioned that previously when patient was working he already had the thrombosis problem, but patient did not take care of it. She commented that the patient used to take Warfarin, but when the patient took Warfarin, he could not eat anything green, then the doctor changed him to the drug Latradecto, but the patient stopped taking them on an unknown date, (does not specify), because the patient forgot to (take them), For this reason the thrombosis was pronounced, she commented that for this reason the patient used stockings on both legs, to help him with the blood circulation in his legs and to prevent it from reaching the heart, but the patient, on an unknown date, stopped using the stockings. Wife of patient mentioned that patient on unknown date was operated on one leg, she does not indicate which one, then thrombosis was pronounced, on unknown date, on the other leg, she does not indicate which one, but the patient could not be operated and another mesh could not be placed because it was quite dangerous and the thrombosis was very advanced. The patient's wife commented that the patient is currently bedridden. She commented that the patient has been suffering from osteoporosis for a long time, she did not mention the date, and for this reason all the patient's therapies were performed at home.

The patient stated that, he had been taking enzalutamide since the beginning of 2021 for the indication of prostate cancer. The patient's wife stated that, the patient does not want to take the enzalutamide medication because he suffered from Alzheimer's disease before using enzalutamide (there was no relation between the Alzheimer disease and the enzalutamide) and that there were days when he was well and others when he was not and his disease made him altered and he does not want to take the medication, the patient did not wanted to take the 4 capsules because of the Alzheimer´s disease. The patient stated that, years ago, before using enzalutamide the patient suffered from thrombosis in his legs, but he had already improved. In the year 2019 or early 2020 (does not give exact date) patient was operated for prostate cancer and at the same time he had a coagulation in the legs and was operated on the left leg placing a mesh so that the clot did not go to the lungs and heart. The patient's wife stated that, when he underwent the operation for prostate cancer, he was given an unspecified medication every 6 months but in the year 2021 (no exact date given) the doctor decided to stop giving him the medication because the patient cried when he was injected and they were afraid that the needle would get stuck in him, so they started using the enzalutamide medication. According to the doctor's order, the dosage of the enzalutamide medication was 4 capsules in the morning,

but the patient did not want to take them and it has been very difficult for them because the patient asked when he would stop taking them, they told the doctor because it was impossible for him to take all 4 at the same time. Since Jun-2022 (reported as approximately 3 months ago as of 08-Sep-2022), the patient took 2 capsules in the morning and during the course of the day he received the other two so that he could take all 4 capsules, the patient has not finished taking the medication as of 08-Sep-2022.

On 29-Sep-2022, the patient reported that, it was difficult for him to ingest the therapy due to his health condition, so the physician suspended the therapy.

As per PQC, there is no quality related issue identified in this case. The report states, "According to the doctor's order, the dosage of the XTANDI medication is 4 capsules in the morning, but the patient does not want to take them and it has been very difficult for them because the patient asks them when he will stop taking them, they told the doctor because it was impossible for him to take all 4 at the same time. The patient's wife says that now they give the patient 2 capsules in the morning and during the course of the day they give him the other two so that he can take all 4 capsules (intentional misuse in dosing frequency)." This is a non-promotional use of the product. The Xtandi product information states, "The recommended dosage of XTANDI is 160 mg administered orally once daily with or without food." This reported incident doesn't meet the definition of a product complaint. A TrackWise number will not be assigned to this case

Upon follow up, it was reported that the patient's wife reported that the patient started taking 2 capsules in the morning and during the course of the day the other two capsules approximately 3 months ago (she did not provide any further information). Patient's wife states that the patient already had Alzheimer's disease before using the enzalutamide medication, indicating that there was no relation between the disease Alzheimer and the medication. Patient's wife stated that the patient indicates that he cannot take the 4 capsules because of the Alzheimer's disease and because the patient indicates that they want to poison him with so much medication. The patient's wife states that the patient has not finished taking the medication.

The patient's wife stated that the patient has no appointments because since 2020, he was bedridden because he has several diseases including osteoporosis, diabetes, Alzheimer's, epileptic seizures, thyroid problems, thrombosis in both legs, among other various diseases that the patient presents, for this reason the patient does not walk, so the doctors come to the patient's home. She comments that the patient the year before last, she does not mention the date, has a thyroid problem, for which he takes medication, she does not specify the name. She mentions that since last year (2023), the patient cannot eat alone and must be given crushed medication and also all the food, because the patient can no longer eat things (solids) because otherwise he chokes. The patient's wife indicates that the enzalutamide medication cuts the soft capsules to give them to the patient in the straw (tube), so that the patient can ingest them, and the doctor was the one who gave the order for the patient to take them in this way. She mentions that the patient in the year 2024, had a heart problem because the patient for several years, she does not mention the date, has a heart murmur so they put a tube in the patient so he could eat, then they took the tube out and since then the patient can no longer eat normal food but everything must be soft. The patient's wife comments that she does not know when the last application of leuprorelin acetate was because the nurse who arrives is the one who knows the information and does not give her details, she also does not know the expiration date and lot number because she does not know the information on the (leuprorelin acetate) injections. The patient's wife believed that, in the month of Dec-2024, it was the patient's turn to receive leuprorelin acetate, but she had not yet been called (to give her a date). She mentioned that the patient only continued with enzalutamide (also reported she did not know the date on which the patient started enzalutamide treatment). During this follow-up the age of the patient was reported as 84-years.

The patient's wife mentions that the patient was no longer using the leuprorelin acetate treatment, she only uses enzalutamide, the patient's wife says that the patient no longer continues to apply leuprorelin acetate as indicated by the Doctor who indicated that it was no longer necessary and in addition to this that the applications of leuprorelin acetate for the patient were painful because he was already advanced in age, but that in relation to enzalutamide it works well for him. She mentions that she does not know the date of the last dose that was applied to the patient in 2024, she does not have the expiry date and batch number, as when they applied the dose of leuprorelin acetate to the patient they did not provide her with this information.

On May-2025, patient is hospitalized for severe generalized deterioration. Family member reports that they have been hospitalized for 15 days and that their condition is critical. No further information is provided regarding symptoms and condition.

The outcome of events unable to eat and thyroid problems was not recovered/ not resolved. The outcome of there are days when he is well and others when he is not and his disease (Alzheimer's disease) makes him altered, heart murmur, had a heart problem and patient can no longer eat things (solids) because otherwise he chokes and Applications of Eligard for the patient were painful was unknown. The outcome of event generalized deterioration was not recovered/ not resolved.

Diseases included Prostate cancer, Thrombosis leg, Alzheimer's disease [approximately in the year 2020, the patient used to take a test with some sticks, but did not take any medication because the condition was hereditary], Epilepsy, Diabetes (Diabetes under control, does not take any medication because it is controlled with diet) and Osteoporosis, procedures included Prostatic operation, Leg operation.

Concomitant medication included APROVEL, XARELTO, KEPPRA [LEVETIRACETAM], PLATELETS, PHENOBARBITAL, Cepraval (does not specify what the patient uses it for (continues with treatment), Latradecto (unknown medication), does not indicate grams or dosage, used it for thrombosis and assumes that Discontinued) and WARFARIN.

No lab test information was provided.

The patient and patient's wife assessed the following events with respect to enzalutamide and leuprorelin acetate:
- There are days when he is well and others when he is not and his disease (Alzheimer's disease) makes him altered (seriousness: Not Reported; causality: Not Assessed)
- Patient received 2 capsules in the morning and during the course of the day the other two so that he can take all 4 capsules (Inappropriate schedule of product administration) (seriousness: Non-serious; causality: Not Assessed)

Continuation Sheet for CIOMS report

- It was impossible to take all 4 at the same time/difficult for him to ingest the therapy (Product use complaint) (seriousness: Not Reported; causality: Not Assessed)
- Unable to eat (seriousness: Serious (disability); causality: Not Assessed)
- Wife cuts soft Xtandi capsules to give to patient in straw/ doctor was the one who gave the order for the patient to take them in this way (Wrong technique in product usage process and off label use) (seriousness: Non serious; causality: Not Assessed)
- Thyroid problems (seriousness: Non serious; causality: Not Assessed)
- Heart Murmur (seriousness: Not reported; causality: Not Assessed)
- Had a heart problem (seriousness: Not reported; causality: Not Assessed)
- Patient can no longer eat things (solids) because otherwise he chokes (seriousness: Not reported; causality: Not Assessed)

The patient's family member assessed the following events with respect to enzalutamide and leuprorelin acetate:
- Generalized deterioration (seriousness: Serious (Hospitalization; Life-threatening); causality: Not related)

The patient's wife assessed the following event with respect to enzalutamide and leuprorelin acetate:
- Applications of Eligard for the patient were painful (seriousness: Not reported; causality: Not Assessed)

Consent to contact patient's wife professional for follow-up information was denied.

Tracking of changes:
26-Aug-2022: Initial information was received.

Follow up information received on 07-Sep-2022: Product quality complaint updated.

This is a patient support program case received by Astellas business partner, Asofarma (a subsidiary of Tecnofarma S. A) from the consumers (patient and patient's wife) on 08-Sep-2022, and was received at Astellas from Asofarma on 09-Sep-2022: Enzalutamide therapy details (start date), event start date (Patient received 2 capsules in the morning and during the course of the day the other two so that he can take all 4 capsules) and clinical description was updated.

This is a patient support program case received by Astellas business partner, Asofarma (a subsidiary of Tecnofarma S. A) from the patient on 29-Sep-2022, and was received at Astellas from Asofarma on 30-Sep-2022: Therapy details of enzalutamide (start date), event verbatim of it was impossible for him to take all 4 at the same time to it was impossible for him to take all 4 at the same time/difficult for him to ingest the therapy and narrative description were updated.

On 10-Oct-2022, information was received from Asofarma (a subsidiary of Tecnofarma S. A). The Asofarma (a subsidiary of Tecnofarma S. A) confirmed the start date of suspect drug as 28-Jan-2019. As per confirmation start date of suspect drug was updated.

Revision to information entered in the database in a prior case version: Upon review on 13-Oct-2022, the following was revised: Event coding for "patient received 2 capsules in the morning and during the course of the day the other two so that he can take all 4 capsules" was updated to once daily dose taken more frequently from intentional misuse in dosing frequency.

Follow up was received by Astellas business partner, Asofarma (a subsidiary of Tecnofarma S. A) from the patient on 06-Jan-2025, and was received at Astellas from Asofarma on 07-Jan-2025: New events (Unable to eat, had a heart problem, Heart Murmur, thyroid problems, Wife cuts soft Xtandi capsules to give to patient in straw/ doctor was the one who gave the order for the patient to take them in this way [Wrong technique in product usage process and off label use] and Patient can no longer eat things (solids) because otherwise he chokes). Medical history, concomitant medication and narrative description were updated.

Follow up was received by Astellas business partner, Asofarma (a subsidiary of Tecnofarma S. A) from the patient's wife on 21-Jan-2025, and was received at Astellas from Asofarma on 22-Jan-2025: Added event (Applications of Eligard for the patient were painful), Eligard stop date and clinical description updated.
------- event
Follow up was received by Astellas business partner, Asofarma (a subsidiary of Tecnofarma S. A) from the patient's wife on 05-Jun-2025, and was received at Astellas from Asofarma on 06-Jun-2025: Added event (Generalized deterioration) and clinical description.

Company Remarks (Sender's Comments) :

Event Information:
Choked on food was assessed as Serious due to Other Medically Important Condition. General physical health deterioration was assessed as Serious due to Caused/Prolonged Hospitalization and Life Threatening. Unable to eat was assessed as Serious due to Disability/Permanent Damage. Heart murmur, Feeling abnormal, Thyroid disorder, Product difficult to swallow, Wrong technique in product usage process, Off label use, Injection site pain, Inappropriate schedule of drug administration and Heart disorder were assessed as Non Serious due to no patient jeopardy reported/ as event does not meet the ICH seriousness criteria. Other Medically Important Condition is based on EMA IME list. Life Threatening is based on considering the baleful nature of the event.

All the events coded to closest available LLT per MEDDRA.

Product: Enzalutamide

Continuation Sheet for CIOMS report

Astellas assessed General physical health deterioration as not related as underlying malignancy provides plausible alternative etiology for the reported event. Astellas assessed Unable to eat, Choked on food, Heart murmur, Feeling abnormal, Heart disorder, Thyroid disorder, as Not Related, as based on the information available, a reasonable possibility to suggest a relationship between the suspect drug and the events cannot be established. Information on final/definitive diagnosis, diagnostic work up, clinical course would be required for comprehensive assessment. Elderly age, pre-existing Alzheimer's disease could be the risk factors. Choked on food was likely due to patient's inability to have solid foods. Product difficult to swallow assessed as Not Related as elderly age and pre-existing Alzheimer's disease provides plausible alternative etiology. Wrong technique in product usage process, Off label use and Inappropriate schedule of drug administration assessed as Not Related based on nature of the events involving human action. Injection site pain was assessed as Not Related as it was reported with reference to Eligard drug.

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

Product-Reaction Level

1) Drug	:	Enzalutamide (Enzalutamide)
Active Substance	:	1) Enzalutamide
Coding Class	:	Verum
Drug Characterization	:	Suspect
Form Strength	:	1) 40 Milligram 2) 40 Milligram
Form of Admin	:	1) Capsule 2) Capsule
Lot Number	:	1) L1881288AJ 2) L1881288AJ
Daily Dose	:	1) 160.0 milligram(s) (160 milligram(s), 1 in 1 Day) (80 milligram(s))
Route of Admin	:	1) Oral 2) Oral
Indications	:	1) Prostate cancer [10060862 - Prostate cancer]
Therapy Dates	:	1) From : 28/Jan/2019 To :Continuing 2) From : /Jun/2022 To :Continuing
Action(s) Taken With Drug	:	Dose not changed

Causality

1) Unable to eat (Unable to eat - 10069830, Feeding disorder - 10061148)

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

2) generalized deterioration (General physical health deterioration - 10049438, General physical health deterioration - 10049438)

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

3) Patient can no longer eat things (solids) because otherwise he chokes (Choked on food - 10008588, Choking - 10008589)

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

4) Heart murmur (Heart murmur - 10019295, Cardiac murmur - 10007586)

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

5) There are days when he is well and others when he is not and his disease (Alzheimer's disease) makes him altered (Feeling abnormal - 10016322, Feeling abnormal - 10016322)

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

6) had a heart problem (Heart disorder - 10019277, Cardiac disorder - 10061024)

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

7) thyroid problems (Thyroid disorder - 10043709, Thyroid disorder - 10043709)

Continuation Sheet for CIOMS report

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

8) Applications of Eligard for the patient were painful (Injection site pain - 10022086, Injection site pain - 10022086)
Causality as per reporter : Not assessed
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

9) It was impossible for him to take all 4 at the same time/difficult for him to ingest the therapy (Product difficult to swallow - 10075696, Product use complaint - 10079400)
Causality as per reporter : Not assessed
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

10) Wife cuts soft Xtandi capsules to give to patient in straw/ doctor was the one who gave the order for the patient to take them in this way (Wrong technique in product usage process - 10076573, Wrong technique in product usage process - 10076573)
Causality as per reporter : Not assessed
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

11) Wife cuts soft Xtandi capsules to give to patient in straw/ doctor was the one who gave the order for the patient to take them in this way (Off label use - 10053762, Off label use - 10053762)
Causality as per reporter : Not assessed
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

12) Patient received 2 capsules in the morning and during the course of the day the other two so that he can take all 4 capsules (Inappropriate schedule of drug administration - 10021597, Inappropriate schedule of product administration - 10081572)
Causality as per reporter : Not assessed
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) Unable to eat
CORE UnLabeled
IB UnLabeled
2) generalized deterioration
CORE UnLabeled
IB UnLabeled
3) Patient can no longer eat things (solids) because otherwise he chokes
CORE UnLabeled
IB UnLabeled
4) Heart murmur
CORE UnLabeled
IB UnLabeled
5) There are days when he is well and others when he is not and his disease (Alzheimer's disease) makes him altered
CORE UnLabeled
IB UnLabeled
6) had a heart problem
CORE UnLabeled
IB UnLabeled
7) thyroid problems
CORE UnLabeled
IB UnLabeled
8) Applications of Eligard for the patient were painful
CORE UnLabeled
IB UnLabeled
9) It was impossible for him to take all 4 at the same time/difficult for him to ingest the therapy
CORE UnLabeled
IB UnLabeled
10) Wife cuts soft Xtandi capsules to give to patient in straw/ doctor was the one who gave the order for the patient to take them in this way
CORE UnLabeled
IB UnLabeled
11) Wife cuts soft Xtandi capsules to give to patient in straw/ doctor was the one who gave the order for the patient to take them in this way

Continuation Sheet for CIOMS report

CORE	UnLabeled
IB	UnLabeled

12) Patient received 2 capsules in the morning and during the course of the day the other two so that he can take all 4 capsules

CORE	UnLabeled
IB	UnLabeled

2) Drug	:	ELIGARD
Active Substance	:	1) LEUPRORELIN ACETATE
Drug Characterization	:	Suspect
Form Strength	:	1) 45 Milligram
Form of Admin	:	1) Injection
Lot Number	:	1) Unknown
Daily Dose	:	1) 0.25 milligram(s) (45 milligram(s), 1 in 6 Month)
Route of Admin	:	1) Subcutaneous
Indications	:	1) Prostate cancer [10060862 - Prostate cancer]
Therapy Dates	:	1) From : 09/Mar/2023 To ://2024
Action(s) Taken With Drug	:	Drug withdrawn

Causality

1) Unable to eat (Unable to eat - 10069830, Feeding disorder - 10061148)

Causality as per reporter	:	Not assessed
Causality as per Mfr	:	Not assessed
ReChallenge	:	Not Applicable

2) generalized deterioration (General physical health deterioration - 10049438, General physical health deterioration - 10049438)

Causality as per reporter	:	Not Related
Causality as per Mfr	:	Not Related

3) Patient can no longer eat things (solids) because otherwise he chokes (Choked on food - 10008588, Choking - 10008589)

Causality as per reporter	:	Not assessed
Causality as per Mfr	:	Not assessed

4) Heart murmur (Heart murmur - 10019295, Cardiac murmur - 10007586)

Causality as per reporter	:	Not assessed
Causality as per Mfr	:	Not assessed

5) There are days when he is well and others when he is not and his disease (Alzheimer's disease) makes him altered (Feeling abnormal - 10016322, Feeling abnormal - 10016322)

Causality as per reporter	:	Not assessed
Causality as per Mfr	:	Not assessed

6) had a heart problem (Heart disorder - 10019277, Cardiac disorder - 10061024)

Causality as per reporter	:	Not assessed
Causality as per Mfr	:	Not assessed

7) thyroid problems (Thyroid disorder - 10043709, Thyroid disorder - 10043709)

Causality as per reporter	:	Not assessed
Causality as per Mfr	:	Not assessed

8) Applications of Eligard for the patient were painful (Injection site pain - 10022086, Injection site pain - 10022086)

Causality as per reporter	:	Not assessed
Causality as per Mfr	:	Not assessed

9) It was impossible for him to take all 4 at the same time/difficult for him to ingest the therapy (Product difficult to swallow - 10075696, Product use complaint - 10079400)

Causality as per reporter	:	Not assessed
Causality as per Mfr	:	Not assessed

10) Wife cuts soft Xtandi capsules to give to patient in straw/ doctor was the one who gave the order for the patient to take them in this way (Wrong technique in product usage process - 10076573, Wrong technique in product usage process - 10076573)

Causality as per reporter	:	Not assessed
Causality as per Mfr	:	Not assessed

11) Wife cuts soft Xtandi capsules to give to patient in straw/ doctor was the one who gave the order for the patient to take them in this way (Off label use - 10053762, Off label use - 10053762)

Causality as per reporter	:	Not assessed
Causality as per Mfr	:	Not assessed

12) Patient received 2 capsules in the morning and during the course of the day the other two so that he can take all 4 capsules (Inappropriate schedule of drug administration - 10021597, Inappropriate schedule of product administration - 10081572)

Causality as per reporter	:	Not assessed
Causality as per Mfr	:	Not assessed

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

Dosage Text :

Drug 1 :Enzalutamide

Continuation Sheet for CIOMS report

2) 80 mg, 2 capsules in the morning and during the day the other two

Drug 2 :ELIGARD

1) ELIGARD 45 MG x 1 LIO x 1 JER

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

1). Drug	:	Aprovel
Active Substance	:	1) IRBESARTAN
Form Strength	:	1) 300 Milligram
Form of Admin	:	1) Capsule
Daily Dose	:	1) 300 milligram(s) (300 milligram(s), 1 in 1 Day)
Route of Admin	:	1) Unknown
Indications	:	1) for pressure and heart [10005728 - Blood pressure abnormal] 2) for pressure and heart [10019277 - Heart disorder]
Dosage Text	:	1) 300 mg, once daily

2). Drug	:	Xarelto
Active Substance	:	1) RIVAROXABAN
Form Strength	:	1) 20 Milligram
Form of Admin	:	1) Capsule
Daily Dose	:	1) 20 milligram(s) (20 milligram(s), 1 in 1 Day)
Route of Admin	:	1) Unknown
Indications	:	1) coagulation [10009731 - Coagulation disorder]
Dosage Text	:	1) 20 mg, once daily

3). Drug	:	Keppra
Active Substance	:	1) LEVETIRACETAM
Form Strength	:	1) 100 Milligram
Form of Admin	:	1) Capsule
Daily Dose	:	1) 100 milligram(s) (100 milligram(s), 1 in 1 Day)
Route of Admin	:	1) Unknown
Indications	:	1) Alzheimer"s [10001896 - Alzheimer's disease]
Dosage Text	:	1) 100 mg, once daily

4). Drug	:	Platelets
Active Substance	:	1) PLATELETS, HUMAN BLOOD
Form Strength	:	
Form of Admin	:	1) Tablet
Daily Dose	:	1) (1000 milligram(s))
Route of Admin	:	1) Unknown
Indications	:	1) epilepsy [10015037 - Epilepsy]
Dosage Text	:	1) takes 1 at night and half a tablet in the morning

5). Drug	:	Phenobarbital
Active Substance	:	1) PHENOBARBITAL
Form Strength	:	
Form of Admin	:	1) Unknown
Daily Dose	:	1) 128.0 milligram(s) (64 milligram(s), 2 in 1 Day)
Route of Admin	:	1) Unknown
Indications	:	1) Drug use for unknown indication [10057097 - Drug use for unknown indication]
Dosage Text	:	1) the morning and at night in conjunction with Cepraval Continued with treatment

6). Drug	:	Warfarin
Active Substance	:	1) WARFARIN
Form Strength	:	
Form of Admin	:	1) Unknown
Daily Dose	:	
Route of Admin	:	1) Unknown
Indications	:	1) thrombosis [10043607 - Thrombosis]
Dosage Text	:	1) does not indicate dose and grams, only that he used it for thrombosis.(Discontinued)

Continuation Sheet for CIOMS report

23. OTHER RELEVANT HISTORY (Continuation...)

2) ALZHEIMER'S DISEASE (10001896 , Alzheimer's disease) (//2020 -) (Continuing : YES)

3) EPILEPSY (10015037 , Epilepsy) (//2020 -) (Continuing : YES)

4) PROSTATE CANCER (10060862 , Prostate cancer) (Continuing : YES)

5) PROSTATE CANCER OPERATION (10061917 , Prostatic operation) (Continuing : NO)

6) OPERATED ON THE LEFT LEG PLACING A MESH SO CLOT DOES NOT GO TO THE LUNGS AND HEART (10051090 , Leg operation) (Continuing : NO)

7) DIABETES (10012594 , Diabetes) (Continuing : YES)

8) OSTEOPOROSIS (10031282 , Osteoporosis) (Continuing : YES)

24a. NAME AND ADDRESS OF MANUFACTURER (Continuation...)

Study # :Enzalutamide_Astellas PSP