

SUSPECT ADVERSE REACTION REPORT	
2024US022142	

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
Masked	PANAMA	Day Masked	Month Masked	Year Masked	91	Male	Day 01	Month Aug	Year 2024	
7+13 DESCRIBE REACTION(S) (including relevant tests/lab data) 1) Fall (Fall (10016173), Fall (10016173)) (07/Oct/2024 -) - Unknown 2) Hip fracture (Hip fracture (10020100), Hip fracture (10020100)) (07/Oct/2024 -) - Unknown 3) Dizziness (Dizziness (10013573), Dizziness (10013573)) (01/Aug/2024 -) - Not Recovered/Not Resolved/Ongoing 4) Right wrist fracture (Wrist fracture (10048049), Wrist fracture (10048049)) (07/Oct/2024 -) - Unknown <div style="text-align: right;">Cont..</div>										
										<input type="checkbox"/> PATIENT DIED <input type="checkbox"/> LIFE THREATENING <input checked="" type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION <input type="checkbox"/> RESULTS IN PERSISTENCE OR SIGNIFICANT DISABILITY/INCAPACITY <input type="checkbox"/> CONGENITAL ANOMALY <input checked="" type="checkbox"/> OTHER MEDICALLY IMPORTANT CONDITION

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S)(include generic name)		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)
1) Enzalutamide (Enzalutamide, Enzalutamide) (Suspect) (Verum) (40 Milligram, Capsule)(Unknown)(40 Milligram, Capsule)(Unknown)		
Cont..		
15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION	
1) 160 milligram(s) (160 milligram(s), 1 in 1 Day)	1) Oral	
2) 160 milligram(s) (160 milligram(s), 1 in 1 Day)	2) Oral	
17. INDICATION(S) FOR USE		
1) Prostate cancer [10060862 - Prostate cancer]		
18. THERAPY DATE(S) (from/to)	19. THERAPY DURATION	
1) (10/Jun/2024 -)		

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
1) Cefalmin(CEFADINE)(400 Milligram, Unknown)
Cont..
23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)
1) HIGH BLOOD PRESSURE (10005727, Blood pressure) (Continuing: Yes)
Cont..

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER		Study Information Study Name: Enzalutamide Patient Support Progr (Cont..)
Name : Astellas Pharma Global Development, Inc.		
2375 Waterview Drive		
Northbrook, IL, 60062-6111, UNITED STATES OF AMERICA		
24. REPORT NULLIFIED	24b. MFR CONTROL NO.	EudraCT Number: Protocol No.: Enzalutamide_Astellas PSP Center No.: Subject Id :
<input type="checkbox"/> YES <input type="checkbox"/> NO	2024US022142	
24c. DATE RECEIVED BY MANUFACTURER	24d. REPORT SOURCE	
10/Jul/2025	<input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL	
DATE OF THIS REPORT	25a. REPORT TYPE	
15/Jul/2025	<input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> FOLLOWUP	

= Continuation attached sheet(s)..

Continuation Sheet for CIOMS report

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

5) Ulcers on his buttock (Skin ulcer (10040943), Skin ulcer (10040943)/(Oct/2024 -) - Unknown)

6) Elevated blood neutrophils (Neutrophil count increased (10029368), Neutrophil count increased (10029368) - Unknown)

7) High eosinophils (Eosinophil count high (10014944), Eosinophil count increased (10014945) - Unknown)

8) Erythrocyte count 4.42 (10³ μ L) (Red blood cell count abnormal (10038151), Red blood cell count abnormal (10038151) - Unknown)

9) Low hemoglobin (Hemoglobin low (10055600), Haemoglobin decreased (10018884) - Unknown)

10) Ear pain (Ear pain (10014020), Ear pain (10014020)(02/Apr/2025 -) - Not Recovered/Not Resolved/Ongoing)

Event Description :

This Patient Support Program case was received by Astellas business partner, Tecnofarma S.A., from a 91 years-old male patient in PANAMA on 02-Aug-2024 and received at Astellas from Tecnofarma S.A., on 03-Aug-2024, 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 patient initiated treatment on 10-Jun-2024.

Study No: Enzalutamide_Astellas PSP; Open-Label study.

The patient received enzalutamide for prostate cancer according to the following dosage regimens: 10-Jun-2024 (also reported as 13-Jun-2024) - (stop date not provided): Oral 160 mg, once daily and (start date not provided) - (ongoing): Oral 160 mg, once daily.

Other suspect drug used was Eligard (leuporelin acetate) for prostate cancer according to the following dosage regimens: 14-Jun-2022 - Aug-2024: Subcutaneous 45 mg, other (every 6 months) and (start date not provided) - (ongoing): Subcutaneous 45 mg, other (every 6 months).

Action taken with enzalutamide in response to event Fall, Hip fracture, Right wrist fracture and Ulcers on his buttock was withdrawn, enzalutamide in response to event dizziness and ear pain was no change, and in response to other event was unknown. Action taken with leuporelin acetate enzalutamide in response to all event was reported as no change.

The patient reports feeling dizzy on 01-Aug-2024. The outcome of dizziness was reported as not recovered/not resolved.

Daughter-in-law of the patient refers that the patient 2 weeks ago, she does not indicate date, by medical order has enzalutamide suspended, because on 07-Oct-2024 patient fell and fractures his hip so they placed him has patient a prosthesis on the right side and also fractured his right wrist, so they placed him a cast, they prescribed pills to patient, she does not remember the name, for the fracture of the hip and right wrist. For this reason, the doctor forbids the patient to take any other medication in pills, other than the one prescribed, she mentions that the patient will finish the medication on Saturday (09-Nov-2024), she does not indicate the name, for this reason, the patient's stepdaughter comments that on Monday (11-Nov-2024), she will start giving the patient the medication (Enzalutamide) again, because the patient must take them for life. Daughter-in-law comments that the patient has had tests of the fractured wrist, hip and ulcers, they mention that the Dermatologist sent the patient to perform an examination (X-rays), they also performed other tests at the patient's home, which results were sent by phone on 06-Nov-2024 and the results indicate that the hip is fine, but the right wrist must be kept in good condition, She also mentions that she took the patient to Paitilla (place) for the X-Ray, which the stepdaughter was supposed to go to pick up on 07-Nov-2024, but she had previously attended but the laboratory was closed, for this reason she still does not have the results.

Stepdaughter mentions that the patient was hospitalized for 1 week in Paitilla (place) due to the fall mentioned above, he is currently at home, he uses a walker to get out of his bed to bathe him and they also ask the patient to hold on to the walker to clean the patient and he also uses a wheelchair because the patient does not walk, the patient's stepdaughter comments that all this happened because of the fall and for the patient it has been like a nightmare, because the patient is 91 years old and he is clear in his mind. The outcome of fall, hip fracture, and right wrist fracture was Unknown.

The patient's stepdaughter says that the patient was diagnosed with ulcers on his buttock, 1 week after the patient had the fall (Oct-2024), but the stepdaughter does not know the reason why the patient got ulcers, she assumes that the patient may have a blood problem or skin problems, because the patient is changed in a diaper, bathed and moved, because the patient has been bedridden since he fell, She comments that she does not believe that it is because of the diaper (that he has ulcers) because they put another one on him that is a different type of cloth, for this reason she assumes that he has something to do with the skin, so the doctor sends the patient for treatment, for this reason the doctor suspended all of the patient's medications until the ulcers are healed and the only medication that the doctor does not suspend is the one for the blood pressure. The patient's stepdaughter comments that the patient is in a program (INCAE) where she attends to the patient at home, they have given the patient therapies and they also give the patient intravenous medications, she does not remember the names, only that they were given to the patient 2 times a day. The patient's stepdaughter mentions that she is concerned about the ulcers that the patient has, she buys Neobol spray and also buys a paste, she does not remember the name, to put on the patient's ulcers on the buttock where the line (of the anus) begins, because some heal and others appear. The outcome of ulcers on his buttock was Unknown.

Patient's stepdaughter mentions that she does not remember when the patient started taking Enzalutamide (she comments that they are large pills), only that before starting the Enzalutamide treatment, he was taking Calutol, she does not remember the grams. She says that the last application of Leuporelin acetate was in Aug-2024, that it was a person who came to the patient's home to apply it, but she does not remember when the first application of Leuporelin acetate was. She does not have the expiration date and lot number of Leuporelin acetate or Enzalutamide, because she comments that Enzalutamide has been suspended because the patient is taking a medication for the infection, she does not remember the name.

Continuation Sheet for CIOMS report

Patient's stepdaughter comments that in Nov-2023, patient had a problem in his right foot, in which it swelled and ugly things came out as if it was a rotten foot, so patient's stepdaughter assumes that it was as if patient had a diabetic foot but patient does not suffer from diabetes and assumed that patient was going to cut his foot, but the doctor saved it twice, once in November and once in December before the doctor died, so the patient should take good care of that foot and apply the creams for life, she does not give the names, because he is currently recovered from the symptoms mentioned above. The patient's stepdaughter assumes that the patient has circulation problems, but that she consulted with the doctor, but comments that the patient does not suffer from circulation because all the tests that were performed, she does not indicate the name, the results have come out well and the patient is not diabetic.

On an unknown date the patient had elevated blood neutrophils, high eosinophils, erythrocyte count 4.42 ($10^3 \mu\text{L}$) and low hemoglobin. And outcome for these events were reported as unknown.

On 02-Apr-2025, the patient's family member reports that, the patient was currently being treated with leuporelin acetate 45 mg lyophilized for injectable suspension at a dose of 45 mg every 6 months since 14-Jun- 2021 for prostate cancer. He continues to take the medication. He also takes enzalutamide 40 mg capsules at a dose of 160 mg daily since 10-Jun-2024 (also reported as 13-Jun-2024) for prostate cancer. He continues to take the medication. The family member reports that he would have an ENT appointment on Friday for ear pain, which began today. The patient had not yet recovered.

On 10-Jul-2025, the patient's family member indicates patient hospitalization on 09-Jul-2025 for circumcision surgery, reporting that he would be going to be discharged on 11-July-2025. It was not possible to confirm whether the circumcision surgery was a scheduled surgery.

Diseases included Blood pressure and Swelling of feet.

Past medications were not reported.

Concomitant medication included CEFALMIN [CEFRADINE], ENALAPRIL, NORBAX M, ATORVASTATIN and CALUTOL.

Lab data included:

Unknown date: Erythrocyte sedimentation rate: 35.00 mm/hour (high).
 Unknown date: Neutrophils: 49.5 % (low)
 Unknown date: Eosinophil: 10.1 % (high)
 Unknown date: Erythrocyte count 4.42 ($10^3 \mu\text{L}$) (low)
 Unknown date: Hemoglobin: 12.1 g/DL (low)
 Unknown date: HCM /CHCM concentration: 31.1 g/DL (low)
 Unknown date: Erythrocyte distribution width (RDW): 15.3% (high)
 Unknown date: C-reactive protein - CRP: 19.44 mg/L (high)
 Unknown date: Prolactin: 0.052 ng/ml (high)

The patient assessed the following event with respect to enzalutamide and leuporelin acetate:

- Dizziness (seriousness: Non-serious; causality: Not Assessed)

The patient's daughter in law assessed the following event with respect to enzalutamide and leuporelin acetate:

- Fall (seriousness: Serious (Hospitalization); causality: Not Assessed)
 - Hip fracture (seriousness: Non serious; causality: Not Assessed)
 - Right wrist fracture (seriousness: Non serious; causality: Not Assessed)

The patient's stepdaughter assessed the following event with respect to enzalutamide and leuporelin acetate:

- Ulcers on his buttock (seriousness: Non serious; causality: Not Assessed)
 - Elevated blood neutrophils (seriousness: Non serious; causality: Not Assessed)
 - High eosinophils (seriousness: Non serious; causality: Not Assessed)
 - Erythrocyte count 4.42 ($10^3 \mu\text{L}$) (seriousness: Non serious; causality: Not Assessed)
 - Low hemoglobin (seriousness: Non serious; causality: Not Assessed)

The patient's family member assessed the following event with respect to enzalutamide and leuporelin acetate:

- Ear pain (seriousness: Non serious; causality: Not Assessed)

Consent to contact Patient and patient's family member for follow-up information was denied.

No additional information was available.

Tracking of changes:

02-Aug-2024: Initial information was received.

 Follow up was received on 08-Nov-2024 with following updates: New event (fall, hip fracture, and right wrist fracture, Ulcers on his buttock, Elevated blood neutrophils, High eosinophils, Erythrocyte count 4.42 ($10^3 \mu\text{L}$) and Low hemoglobin) was added. Medical history, concomitant medication details, enzalutamide therapy details, action taken, eligard action taken, lab data, and narrative description was updated.

Continuation Sheet for CIOMS report

Follow up information was received by Astellas business partner, Asofarma, on 02-Apr-2025 from a consumer (patient's family member) and was received at Astellas from Asofarma on 03-Apr-2025: Enzalutamide and leuprorelin acetate therapy details updated, new event (Ear pain) added, concomitant medications ongoing status removed and case description updated.

Follow up information was received by Astellas business partner, Asofarma, on 10-Jul-2025 from a consumer (patient's family member) and was received at Astellas from Asofarma on 11-Jul-2025: Clinical description updated.

Company Remarks (Sender's Comments) :

Event Information:

Hip fracture and Wrist fracture were assessed as Serious due to Other Medically Important Condition.

Fall was assessed as Serious due to Caused/Prolonged Hospitalization.

Neutrophil count increased, Eosinophil count high, Red blood cell count abnormal, Hemoglobin low, Dizziness, Skin ulcer and Ear pain were assessed as Non Serious.

Other Medically Important Condition is based on nature of the events.

Non-Serious is based on events not meeting ICH seriousness criteria.

All events were coded with closest available MedDRA terms.

Product: Enzalutamide

Astellas assessed Dizziness as Related based on plausible temporal relationship. Patients advanced age, underlying malignancy and co-suspect Leuprorelin acetate could be the confounders. Astellas assessed Fall, Hip fracture, Wrist fracture, Skin ulcer, Neutrophil count increased, Eosinophil count high, Red blood cell count abnormal, Hemoglobin low and Ear pain 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 sequence of events prior to Fall and circumstances around it would be required for further assessment. Hip fracture, Wrist fracture was due to Fall. Patients advanced age and underlying malignancy could be the risk factors for Neutrophil count increased, Eosinophil count high, Red blood cell count abnormal and Hemoglobin low. Elderly age could be risk factor for Fall. Final diagnosis and relevant diagnostics would be required for Skin ulcer and Ear pain pertaining to further assessment.

Additional Information (Continuation...)

Laboratory Data :

Unknown date: Erythrocyte sedimentation rate: 35.00 mm/hour (high).

Unknown date: Neutrophils: 49.5 % (low)

Unknown date: Eosinophil: 10.1 % (high)

Unknown date: Erythrocyte count 4.42 (10³ µL) (low)

Unknown date: Hemoglobin: 12.1 g/DL (low)

Unknown date: HCM /CHCM concentration: 31.1 g/DL (low)

Unknown date: Erythrocyte distribution width (RDW): 15.3% (high)

Unknown date: C-reactive protein - CRP: 19.44 mg/L (high)

Unknown date: Prolactin: 0.052 ng/ml (high)

Lab Result :

Test Name	Test Date	Test Result	Normal Value
EOSINOPHIL	Unknown	10.1 % percent	
ERYTHROCYTE COUNT	Unknown	4.42 10 thousand cells per microlitre	
ERYTHROCYTE DISTRIBUTION WIDTH (RDW)	Unknown	15.3 % percent	
ERYTHROCYTE SEDIMENTATION RATE	Unknown		
HCM /CHCM CONCENTRATION	Unknown	31.1 gram per decilitre	
HEMOGLOBIN	Unknown	12.1 gram per decilitre	
NEUTROPHILS	Unknown	49.5 % percent	
PROLACTIN	Unknown	0.052 nanogram per milliiter	

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

Result Unstructured Data (free text) : 35.00 mm/hour (high)

Test Date: Unknown

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) Unknown 2) Unknown
Daily Dose	: 1) 160 milligram(s) (160 milligram(s), 1 in 1 Day) 2) 160 milligram(s) (160 milligram(s), 1 in 1 Day)
Route of Admin	: 1) Oral 2) Oral
Indications	: 1) Prostate cancer [10060862 - Prostate cancer]
Therapy Dates	: 1) From : 10/Jun/2024 To :
Action(s) Taken With Drug	: Drug withdrawn

Causality

- 1) Fall (Fall - 10016173, Fall - 10016173)
 - Causality as per reporter : Not assessed
 - Causality as per Mfr : Not Related
 - DeChallenge : Not applicable
 - ReChallenge : Not Applicable
- 2) Hip fracture (Hip fracture - 10020100, Hip fracture - 10020100)
 - Causality as per reporter : Not assessed
 - Causality as per Mfr : Not Related
 - DeChallenge : Not applicable
 - ReChallenge : Not Applicable
- 3) Dizziness (Dizziness - 10013573, Dizziness - 10013573)
 - Causality as per reporter : Not assessed
 - Causality as per Mfr : Related
 - DeChallenge : Not applicable
 - ReChallenge : Not Applicable
- 4) Right wrist fracture (Wrist fracture - 10048049, Wrist fracture - 10048049)
 - Causality as per reporter : Not assessed
 - Causality as per Mfr : Not Related
 - DeChallenge : Not applicable
 - ReChallenge : Not Applicable
- 5) Ulcers on his buttock (Skin ulcer - 10040943, Skin ulcer - 10040943)
 - Causality as per reporter : Not assessed
 - Causality as per Mfr : Not Related
 - DeChallenge : Not applicable
- 6) Elevated blood neutrophils (Neutrophil count increased - 10029368, Neutrophil count increased - 10029368)
 - Causality as per reporter : Not assessed
 - Causality as per Mfr : Not Related
- 7) High eosinophils (Eosinophil count high - 10014944, Eosinophil count increased - 10014945)
 - Causality as per reporter : Not assessed
 - Causality as per Mfr : Not Related
- 8) Erythrocyte count 4.42 (10³ µL) (Red blood cell count abnormal - 10038151, Red blood cell count abnormal - 10038151)
 - Causality as per reporter : Not assessed
 - Causality as per Mfr : Not Related
- 9) Low hemoglobin (Hemoglobin low - 10055600, Haemoglobin decreased - 10018884)
 - Causality as per reporter : Not assessed
 - Causality as per Mfr : Not Related

Continuation Sheet for CIOMS report

10) Ear pain (Ear pain - 10014020, Ear pain - 10014020)

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

Labeling :

1) Fall
 CORE Labeled
 IB Labeled
 2) Hip fracture
 CORE Labeled
 IB Labeled
 3) Dizziness
 CORE UnLabeled
 IB UnLabeled
 4) Right wrist fracture
 CORE Labeled
 IB Labeled
 5) Ulcers on his buttock
 CORE UnLabeled
 IB UnLabeled
 6) Elevated blood neutrophils
 CORE UnLabeled
 IB UnLabeled
 7) High eosinophils
 CORE UnLabeled
 IB UnLabeled
 8) Erythrocyte count 4.42 (10³ µL)
 CORE UnLabeled
 IB UnLabeled
 9) Low hemoglobin
 CORE UnLabeled
 IB UnLabeled
 10) Ear pain
 CORE UnLabeled
 IB UnLabeled

2) Drug : Eligard
 Active Substance : 1) LEUPRORELIN ACETATE
 Drug Characterization : Suspect
 Form Strength : 1) 45 Milligram
 2) 45 Milligram
 Form of Admin : 1) Powder for suspension for injection
 2) Powder for suspension for injection
 Lot Number : 1) Unknown
 2) Unknown
 Daily Dose : 1) 0.25 milligram(s) (45 milligram(s), 1 in 6 Month)
 2) 0.25 milligram(s) (45 milligram(s), 1 in 6 Month)
 Route of Admin : 1) Subcutaneous
 2) Subcutaneous
 Indications : 1) Prostate cancer [10060862 - Prostate cancer]
 Therapy Dates : 1) From : 14/Jun/2021 To :/Aug/2024
 Action(s) Taken With Drug : Unknown

Causality

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

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

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

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

Continuation Sheet for CIOMS report

- 3) Dizziness (Dizziness - 10013573, Dizziness - 10013573)
 Causality as per reporter : Not assessed
 Causality as per Mfr : Not assessed
 DeChallenge : Not applicable
 ReChallenge : Not Applicable
- 4) Right wrist fracture (Wrist fracture - 10048049, Wrist fracture - 10048049)
 Causality as per reporter : Not assessed
 Causality as per Mfr : Not assessed
 DeChallenge : Not applicable
 ReChallenge : Not Applicable
- 5) Ulcers on his buttock (Skin ulcer - 10040943, Skin ulcer - 10040943)
 Causality as per reporter : Not assessed
 Causality as per Mfr : Not assessed
 DeChallenge : Not applicable
 ReChallenge : Not Applicable
- 6) Elevated blood neutrophils (Neutrophil count increased - 10029368, Neutrophil count increased - 10029368)
 Causality as per reporter : Not assessed
 Causality as per Mfr : Not assessed
 DeChallenge : Not applicable
 ReChallenge : Not Applicable
- 7) High eosinophils (Eosinophil count high - 10014944, Eosinophil count increased - 10014945)
 Causality as per reporter : Not assessed
 Causality as per Mfr : Not assessed
 DeChallenge : Not applicable
 ReChallenge : Not Applicable
- 8) Erythrocyte count 4.42 (10³ µL) (Red blood cell count abnormal - 10038151, Red blood cell count abnormal - 10038151)
 Causality as per reporter : Not assessed
 Causality as per Mfr : Not assessed
 DeChallenge : Not applicable
 ReChallenge : Not Applicable
- 9) Low hemoglobin (Hemoglobin low - 10055600, Haemoglobin decreased - 10018884)
 Causality as per reporter : Not assessed
 Causality as per Mfr : Not assessed
 DeChallenge : Not applicable
 ReChallenge : Not Applicable
- 10) Ear pain (Ear pain - 10014020, Ear pain - 10014020)
 Causality as per reporter : Not assessed
 Causality as per Mfr : Not assessed
 DeChallenge : Not applicable
 ReChallenge : Not Applicable

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

Dosage Text :

Drug 2 :ELIGARD

1) Injection, powder, lyophilized, for suspension

2) Injection, powder, lyophilized, for suspension

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

- 1). Drug : Cefalmin
 Active Substance : 1) CEFRADINE
 Form Strength : 1) 400 Milligram
 Form of Admin : 1) Unknown
 Daily Dose : 1) 800.0 milligram(s) (400 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) take 1 in the morning and 1 in the evening
- 2). Drug : Enalapril
 Active Substance : 1) ENALAPRIL
 Form Strength :
 Form of Admin : 1) Unknown
 Daily Dose : 1) (2 in 1 Day)
 Route of Admin : 1) Unknown

Continuation Sheet for CIOMS report

Indications : 1) high blood pressure [10005750 - Blood pressure increased]
 Dosage Text : 1) does not remember grams, takes 1 in the morning and 1 at night

3). Drug : Norbax
 Active Substance : 1) METRONIDAZOLE BENZOATE
 2) NORFLOXACIN
 Form Strength :
 Form of Admin : 1) Unknown
 Daily Dose : 1) 2.0 dosage form (2 dosage form, 1 in 1 Day)
 Route of Admin : 1) Unknown
 Indications : 1) high blood pressure [10005750 - Blood pressure increased]
 Dosage Text : 1) does not remember grams, takes 2 in the morning

4). Drug : Atorvastatin
 Active Substance : 1) ATORVASTATIN
 Form Strength :
 Form of Admin : 1) Unknown
 Daily Dose : 1) (1 in 1 Day)
 Route of Admin : 1) Unknown
 Indications : 1) Drug use for unknown indication [10057097 - Drug use for unknown indication]
 Dosage Text : 1) does not remember grams, takes 1 in the morning

5). Drug : Calutol
 Active Substance : 1) BICALUTAMIDE
 Form Strength :
 Form of Admin : 1) Unknown
 Daily Dose :
 Route of Admin : 1) Unknown
 Indications : 1) prostate cancer [10060862 - Prostate cancer]
 Dosage Text : 1) does not refer grams or dosage

23. OTHER RELEVANT HISTORY (Continuation...)

2) PROBLEM IN HIS RIGHT FOOT, IN WHICH IT SWELLED AND UGLY THINGS CAME OUT AS IF IT WAS A ROTTEN FOOT (10042693 , Swelling of feet) (Continuing : NO)

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

Study # :Enzalutamide_Astellas PSP