

SUSPECT ADVERSE REACTION REPORT												
	2021US010520											

## I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) Masked	1a. COUNTRY PANAMA	2. DATE OF BIRTH Day Month Year Masked Masked Masked			2a. AGE Years 79	3. SEX Male	4-6 REACTION ONSET Day Month Year 15 Feb 2021			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION  <input type="checkbox"/> PATIENT DIED <input type="checkbox"/> LIFE THREATENING <input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION <input type="checkbox"/> RESULTS IN PERSISTENCE OR SIGNIFICANT DISABILITY/INCAPACITY <input type="checkbox"/> CONGENITAL ANOMALY <input type="checkbox"/> OTHER MEDICALLY IMPORTANT CONDITION
7+13 DESCRIBE REACTION(S) (including relevant tests/lab data) 1) Dizziness (Dizziness (10013573), Dizziness (10013573)) (08/Mar/2021 - ) - Recovered/Resolved With Sequelae 2) Irritation in both elbows in the upper part (skin irritation) as if it were a rash (Skin irritation (10040880), Skin irritation (10040880)) (06/Jun/2023 - ) - Not Recovered/Not Resolved/Ongoing 3) He feels his right hand asleep (Numbness in hand (10049681), Hypoaesthesia (10020937)) (/Jun/2023 - ) - Not Recovered/Not Resolved/Ongoing 4) Hot flashes he feels in both feet and in the body (Hot flashes (10020407), Hot flush (10060800)) Not Recovered/Not Resolved/Ongoing										

Cont..

## II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) 1) Enzalutamide (Enzalutamide, Enzalutamide) (Suspect) (Verum) (40 Milligram, Capsule) (L 1939652AAC) (40 Milligram, Capsule) (L 2081024AE - 730979517)		20. DID EVENT ABATE AFTER STOPPING DRUG?  <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
15. DAILY DOSE(S) 1) 40.0 milligram(s) (40 milligram(s), 1 in 1 Day) 2) 40.0 milligram(s) (40 milligram(s), 1 in 1 Day)		
16. ROUTE(S) OF ADMINISTRATION 1) Oral 2) Oral		21. DID EVENT REAPPEAR AFTER REINTRODUCTION  <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA (NA : Not Applicable)
17. INDICATION(S) FOR USE 1) prostate cancer [10060862 - Prostate cancer]		
18. THERAPY DATE(S) (from/to) 1) (15/Feb/2021 - )	19. THERAPY DURATION	

## III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction) No concomitants used/reported
23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergies, pregnancy with last month of period, etc.) 1) FIRST PROBLEM WITH HIS RIGHT KNEE/WEAR AND TEAR ON HIS RIGHT KNEE (10049032, Knee injury) (Continuing: No)

## 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 <input type="checkbox"/> YES <input type="checkbox"/> NO	24b. MFR CONTROL NO. 2021US010520		
24c. DATE RECEIVED BY MANUFACTURER 30/Jul/2025	24d. REPORT SOURCE <input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL		
DATE OF THIS REPORT 07/Aug/2025	25a. REPORT TYPE <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) Fall (Fall (10016173), Fall (10016173)(14/May/2025 - ) - Recovering/Resolving)

6) Pains that still bother him in the rib (Rib pain (10048722), Musculoskeletal chest pain (10050819)(14/May/2025 - ) - Recovering/Resolving)

7) Pains that still bother him in the shoulder (Shoulder pain (10040617), Arthralgia (10003239)(14/May/2025 - ) - Not Recovered/Not Resolved/  
Ongoing)

8) Wear and tear on the right knee when flexing the knee (Knee injury (10049032), Joint injury (10060820)(/May/2025 - ) - Unknown)

9) Patient took 40 mg xtandi daily/Underdosing (Underdose (10057362), Underdose (10057362)(15/Feb/2021 - ) - Unknown)

## Event Description :

This Patient Support Program case was received by Astellas business partner, Tecnofarma S.A., from received from a Consumer or other non health professional in PANAMA on 18-Mar-2021 and received at Astellas from Tecnofarma S.A., on 19-Mar-2021, concerning a 79 Year(s) old (reported 81 years-old; now reported as 83 Year(s) old) Male patient, enrolled in post-marketing study: Enzalutamide Patient Support Program who was on Xtandi (enzalutamide), Capsule (40 milligram(s), 1 every 1 Day). Indication for use was Prostate cancer. The lot numbers were L1939652AAC and L2081024AE - 730979517. The patient initiated treatment on 15-Feb-2021.

Study No: Enzalutamide\_Astellas PSP; Open-Label study.

The patient received enzalutamide for prostate cancer according to the following dosage regimens: 15-Feb-2021 - (stop date not provided): Oral, 40 mg, once daily and 28-Feb-2022 - (ongoing): Oral 40 mg, once daily. The lot# L1939652AAC and expiry date: 30-Apr-2024 and Lot# L2081024AE - 7309795173 and expiry date: Feb-2026.

Action taken with enzalutamide in response to event dizziness was unknown and in response to other events was dose not changed.

The patient received Eligard (leuporelin) for prostate cancer according to the following dosage regimens: 26-Mar-2019 - Apr-2023: unknown route, dose, and frequency; 28-Feb-2022 - (stop date not provided): Subcutaneous 45 mg every 6 months and 19-Jun-2025 - (ongoing): unknown route, dose, and frequency. (Patient indicates that they received it a month or a month and a half ago and are waiting to see their doctor to determine when to reapply. Their appointment is today, but due to rain, they don't expect to go.) Lot# L2081024AE; Expiry date- Feb-2026.

Action taken with leuporelin treatment in response to the events was dose not changed.

Since 15-Feb-2021, the patient took 40 mg enzalutamide daily, which was considered as underdose. Since 08-Mar-2021 the patient had dizziness (also reported never experienced dizziness).

The patient indicated that he also used the leuporelin medication (he does not provide a start date) but his last application was in Apr-2023, he does not have the lot number and expiration date of the leuporelin medication, the doctor was the one who applied it and he discarded the box. The patient reported that on 06-Jun-2023, he started with irritation in both elbows in the upper part (skin irritation) as if it were a rash. On 08-Jun-2023 he would go to the doctor for a consultation and to be prescribed some medication. He does not currently use any medication for this symptom. The patient comments that two weeks ago on 06-May-2023 he had the same irritation mentioned above, but he applied a cocoa cream and it had disappeared.

The patient refers that the event "irritation in both elbows in the upper part (skin irritation) as if it were a rash" was not related to the enzalutamide medication, that probably these symptoms were due to the heat, the patient commented that he no longer went to consult with the physician that was scheduled for 08-Jun-2023, because the day after the event was reported he no longer had irritation. The patient refers that the irritation on both elbows in the upper part (skin irritation) was not similar to some kind of eruption, which was like a rash. It was reported that the drug enzalutamide was prescribed by his physician for prostate cancer. The patient still have the irritation, especially in the morning.

The patient had an appointment with his physician, the patient consulted him about some hot flashes he feels in both feet and in the body (sensation of heat), the physician commented to the patient that it was due to the side effects of the enzalutamide medication, that it was normal to feel these symptoms and that it would soon pass.

Patient refers that 4 to 5 days ago, he does not remember the date, he feels his right hand asleep (numbness in hand), it does not cause his malaise, but it causes his discomfort because when he grabs an object, he does not feel that he is holding it in his hand. He has not consulted with his doctor about this symptom because he has not had an appointment, but he will do so on Tuesday, 04-Jul-2023.

Patient mentions that, on 14-May-2025, he suffered a fall leaving the bathroom, he refers that at the moment he left the bathroom he grabbed a lever or curtain rods (it is unknown what exactly he is referring to), he mentions that the reason for the fall was because the carpet moved causing him to fall, patient refers that he was conscious, although he comments that because of the fall he hurt his right and left hand, since the patient comments that he placed both hands in front of him so that his head would not hit the toilet, he also comments that in his stomach in the part of the left rib he received the blow on the tip of the toilet, which is a pain that he still has, for this reason he cannot go out to the street to request his next box of Xtandi, he will probably request it on Tuesday. On 25-Feb-2025 the patient went to the emergency hospital where he had an x-ray, which revealed that there was no fracture, but he did have pain. Patient agrees to be contacted and treating physician for future follow-up.

## Continuation Sheet for CIOMS report

On 19-May-2025, the patient reported that, from the fall of 14-May-2025, he still did not feel recovered because he still had pains that still bother him in the rib and shoulder so he must rest constantly, but he walks and performs his activities, he mentions that he managed not to hit his face. Patient agrees to be contacted and treating physician for future follow-up.

At time of report on 16-Jul-2025 the patient reported the patient fingers still go numb. The patient can move hand, but when the patient touch or pick up something, the patient can't feel anything. The patient continued to experience hot flashes in the right foot near the knee. The patient feel pain in my right knee when the patient bend the knee, and it causes windpipe damage (the patient think that's what caused the patient to fall). The patient have not had any more falls. The patient still hurts, not every day, but it comes and goes. Shoulder pain still bothers the patient, not every day, but the pain comes and goes. The patient lower back also hurts. This pain started a week ago. The doctor said it's muscle pain.

On an unknown date in May-2025, the patient had wear and tear on the right knee when flexing the knee.

Upon follow up, dizziness was its a rare condition that he can't explain. Sometimes his right knee hurts, but he's never fallen before. He was leaving the bathroom, then opening the shower curtains (the door wasn't closed). He grabbed the top part where the curtain was, put his right foot on the floor, and lifted the other foot to get out. At that moment, he felt like he was going to fall. Right then, he fell, hit the toilet, put his hand up to avoid hitting his face on the toilet, and hit his left rib when he fell. He hadn't felt the impact on his ribs at that moment. He indicates that his left rib area hurts. They ran tests on him, but he doesn't have any fractures. The center tells him it's due to the impact and his age, but the patient says he feels something. It's strange because it feels like someone hit him with a stick, but not to say that something is broken. Now he's feeling where he hit himself, but when he went to the middle, he didn't feel any pain. He later returned to the doctor because his daughter told him, and they gave him a painkiller. He feels like his left rib is rubbing (but he doesn't know what it is). The doctor told him it's due to inflammation, but he's felt this way since approximately June 22nd. Sometimes he gets up and doesn't feel anything, but other days he does. He puts his hand to feel it, and the doctor also gives him a prescription, but he says it was due to the fall and his age. He's recovery. The doctor says he has nothing, but he can feel it.

The patient indicated it was on Wednesday, 14- Jun-2025 [discrepant information; correct date is 14-May-2025]. This is believed to be the case, as there was no receipt at the time of the consultation. He had no further falls.

Wear and tear on his right knee when bending it: Patient indicates that 15 years ago, when he was getting out of the car, he had his first problem with his right knee. The doctor gave him an injection. It was supposed to be two, but a doctor told him that the second dose could give him cancer. He had no problems with his knee for 15 years until the day of the fall, when he stood firmly on that foot.

He doesn't know what's happening. Every time he goes to the doctor, there are pauses, and they tell him that if it doesn't bother him, nothing should be done. They tell him that it's not good to cut because, due to his age, healing can take time.

The outcome of event Dizziness was recovered/resolved with sequelae. The outcome of event irritation in both elbows in the upper part (skin irritation) as if it were a rash, He feels his right hand asleep, Hot flashes he feels in both feet and in the body, and Pains that still bother him in the shoulder were not recovered/not resolved. The outcome of event fall and Pains that still bother him in the rib was recovering. The outcome of Wear and tear on the right knee when flexing the knee was unknown.

Diseases included Knee injury.

Past medications included unspecified injection for first problem with his right knee/wear and tear on his right knee.

Concomitant medication included Contractile plus 4mg: take 1tablet every 12 hours, for pain.

Lab data included:

On 25-Feb-2025, X-RAY: no fracture.

The consumer assessed the following event with respect to enzalutamide and Eligard (leuporelin):

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

The patient assessed the following events with respect to enzalutamide:

- Hot flashes he feels in both feet and in the body (seriousness: Non- serious; causality: Related)
- Irritation in both elbows in the upper part (skin irritation) as if it were a rash (seriousness: Non-serious; causality: Not Related)
- Patient took 40 mg Xtandi daily/Underdosing (seriousness: Not Reported; causality: Not Assessed)
- He feels his right hand asleep (seriousness: Non-serious; causality: Related)
- Fall (seriousness: Non-serious; causality: Related)
- Pains that still bother him in the rib (seriousness: Non-serious; causality: Not Assessed)
- Pains that still bother him in the shoulder (seriousness: Non-serious; causality: Related)
- Wear and tear on the right knee when flexing the knee (seriousness: Non-serious; causality: Not Assessed)

The patient assessed the following events with respect to Eligard (leuporelin):

- Hot flashes he feels in both feet and in the body (seriousness: Non- serious; causality: Not Assessed)
- Irritation in both elbows in the upper part (skin irritation) as if it were a rash (seriousness: Non-serious; causality: Not Assessed)
- Patient took 40 mg Xtandi daily/Underdosing (seriousness: Not Reported; causality: Not Assessed)
- He feels his right hand asleep (seriousness: Non-serious; causality: Related)
- Fall (seriousness: Non-serious; causality: Related)
- Pains that still bother him in the rib (seriousness: Non-serious; causality: Not Assessed)
- Pains that still bother him in the shoulder (seriousness: Non-serious; causality: Related)

## Continuation Sheet for CIOMS report

- Wear and tear on the right knee when flexing the knee (seriousness: Non-serious; causality: Not Assessed)

Consent to contact Patient for follow-up information was provided and denied for the consumer.

## Tracking of changes:

18-Mar-2021: Initial information was received.

Follow-up information received on 26-Apr-2021. Confirmation of country of incidence, non-significant information.

This patient support program case was received by Astellas business partner Asofarma (a subsidiary of Tecnofarma S. A) on 08-Jun-2023 from a patient and was received at Astellas from Asofarma on 08-Jun-2023. The patient was enrolled in Astellas sponsored patient support program titled "ASOFARMA A TU LADO": Added the enzalutamide therapy details (additional dosage regimen, lot number and expiration dates), co-suspect Eligard (leuprorelin) details, new event of irritation in both elbows in the upper part (skin irritation) as if it were a rash. Updated the report type from spontaneous to sponsored study, action taken with suspect drugs and narrative description.

This patient support program case was received by Astellas business partner Asofarma (a subsidiary of Tecnofarma S. A) on 20-Jun-2023 from a patient and was received at Astellas from Asofarma on 20-Jun-2023: New event "hot flashes he feels in both feet and in the body" added, event details of "irritation in both elbows in the upper part (skin irritation) as if it were a rash" (outcome, causality) and narrative was updated.

This patient support program case was received by Astellas business partner Asofarma (a subsidiary of Tecnofarma S. A) on 29-Jun-2023 from a patient and was received at Astellas from Asofarma on 30-Jun-2023: Added new event He feels his right hand asleep, event outcome and causality of Hot flashes he feels in both feet and in the body. Updated clinical information.

On 12-Jul-2023 and 13-Jul-2023 confirmation was received that no additional information was available.

On 31-Jul-2023 confirmation was received that no additional information was available.

This information case was received by Astellas business partner Asofarma (a subsidiary of Tecnofarma S. A) on 27-Feb-2025 from a patient and was received at Astellas from Asofarma on 28-Feb-2025: concomitant medications, Irritation in both elbows in the upper part (skin irritation) as if it were a rash event onset date, lab data, outcome (Hot flashes he feels in both feet and in the body and Irritation in both elbows in the upper part (skin irritation) as if it were a rash) and case description updated. New event fall added.

This patient support program case was received by Astellas business partner Asofarma (a subsidiary of Tecnofarma S. A) on 19-May-2025 from a patient and was received at Astellas from Asofarma on 20-May-2025: New events (Pains that still bother him in the rib and Pains that still bother him in the shoulder) added, patient's age updated, consent to contact patient for follow-up information updated from no to yes and case description updated.

This information case was received by Astellas business partner Asofarma (a subsidiary of Tecnofarma S. A) on 16-Jul-2025 from a patient and was received at Astellas from Asofarma on 17-Jul-2025: Added even wear and tear on the right knee when flexing the knee. Updated enzalutamide therapy details, event Hot flashes he feels in both feet and in the body, He feels his right hand asleep, Irritation in both elbows in the upper part (skin irritation) as if it were a rash outcome from unknown to not recovered, Dizziness outcome from unknown to Recovered / resolved with sequelae, fall from not recovered to recovered, Updated verbatim from Patient took 40 mg Xtandi daily to Patient took 40 mg Xtandi daily/Underdosing, event He feels his right hand asleep, Pains that still bother him in the shoulder and Fall causality from not assessed to related and case description.

This information case was received by Astellas business partner Asofarma (a subsidiary of Tecnofarma S. A) on 30-Jul-2025 from a patient and was received at Astellas from Asofarma on 31-Jul-2025: patient's medical history, historical drug, co suspect Eligard [additional dosage regimen, lot number and expiry date], event onset date and outcome for [Wear and tear on the right knee when flexing the knee], Outcome of fall was updated to recovering, onset date, and dizziness related information, narrative description was updated.

Company Remarks (Sender's Comments) :

## Event Information:

Hot flashes, Knee injury, Underdose, Dizziness, Numbness in hand, Skin irritation, Fall, Rib pain and Shoulder pain were assessed as Non Serious. Non-Serious is due to no patient jeopardy reported/ as event does not meet the ICH seriousness criteria.

All the events coded to closest available LLT per MEDDRA.

## Product: Enzalutamide

Astellas assessed Dizziness, Skin irritation, Numbness in hand and Hot flashes as Related based on temporal association. Elderly age and underlying malignancy could be confounders for Dizziness and Numbness in hand. Exposure to heat is a confounder for Skin irritation. Eligard is confounder for the events.

Astellas assessed Knee injury as Not Related which had occurred during flexing the knee, need additional information on event for better assessment. Fall as not related as there is no evidence that drug caused the fall. Elderly age and concurrent dizziness are risk factors. Events Rib pain and Shoulder pain were assessed as not related as these were due to fall in this elderly patient. Underdose was assessed as Not Related, as it was due to human action.

Additional Information (Continuation...)

Laboratory Data :

25-Feb-2025: X-Ray: no fracture

Lab Result :

Test Name	Test Date	Test Result	Normal Value
X-RAY	25/Feb/2025		

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

1) Test Name: X-RAY

Result Unstructured Data (free text) : no fracture

Test Date: 25/Feb/2025

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) L1939652AAC 2) L 2081024AE - 730979517
Daily Dose	: 1) 40.0 milligram(s) (40 milligram(s), 1 in 1 Day) 2) 40.0 milligram(s) (40 milligram(s), 1 in 1 Day)
Route of Admin	: 1) Oral 2) Oral
Indications	: 1) prostate cancer [10060862 - Prostate cancer]
Therapy Dates	: 1) From : 15/Feb/2021 To :Unknown 2) From : 28/Feb/2022 To :Unknown
Action(s) Taken With Drug	: Unknown

## Causality

- 1) Dizziness (Dizziness - 10013573, Dizziness - 10013573 )  
Causality as per reporter : Not assessed  
Causality as per Mfr : Related
- 2) Irritation in both elbows in the upper part (skin irritation) as if it were a rash (Skin irritation - 10040880, Skin irritation - 10040880 )  
Causality as per reporter : Not Related  
Causality as per Mfr : Related  
DeChallenge : Not applicable  
ReChallenge : Not Applicable
- 3) He feels his right hand asleep (Numbness in hand - 10049681, Hypoaesthesia - 10020937 )  
Causality as per reporter : Related  
Causality as per Mfr : Related  
DeChallenge : Not applicable  
ReChallenge : Not Applicable
- 4) Hot flashes he feels in both feet and in the body (Hot flashes - 10020407, Hot flush - 10060800 )  
Causality as per reporter : Related  
Causality as per Mfr : Related
- 5) Fall (Fall - 10016173, Fall - 10016173 )  
Causality as per reporter : Related  
Causality as per Mfr : Not Related  
DeChallenge : Not applicable  
ReChallenge : Not Applicable
- 6) Pains that still bother him in the rib (Rib pain - 10048722, Musculoskeletal chest pain - 10050819 )  
Causality as per reporter : Not assessed  
Causality as per Mfr : Not Related  
DeChallenge : Not applicable  
ReChallenge : Not Applicable

7) Pains that still bother him in the shoulder (Shoulder pain - 10040617, Arthralgia - 10003239 )

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

8) Wear and tear on the right knee when flexing the knee (Knee injury - 10049032, Joint injury - 10060820 )

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

9) Patient took 40 mg xtandi daily/Underdosing (Underdose - 10057362, Underdose - 10057362 )

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

1) Dizziness		
CORE		UnLabeled
IB		UnLabeled
2) Irritation in both elbows in the upper part (skin irritation) as if it were a rash		
CORE		UnLabeled
IB		UnLabeled
3) He feels his right hand asleep		
CORE		UnLabeled
IB		UnLabeled
4) Hot flashes he feels in both feet and in the body		
CORE		Labeled
IB		UnLabeled
5) Fall		
CORE		Labeled
IB		Labeled
6) Pains that still bother him in the rib		
CORE		UnLabeled
IB		UnLabeled
7) Pains that still bother him in the shoulder		
CORE		UnLabeled
IB		UnLabeled
8) Wear and tear on the right knee when flexing the knee		
CORE		UnLabeled
IB		UnLabeled
9) Patient took 40 mg xtandi daily/Underdosing		
CORE		UnLabeled
IB		UnLabeled

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## Continuation Sheet for CIOMS report

Action(s) Taken With Drug : Dose not changed

## Causality

- 1) Dizziness (Dizziness - 10013573, Dizziness - 10013573 )
  - Causality as per reporter : Not assessed
  - Causality as per Mfr : Not assessed
  - DeChallenge : Not applicable
  - ReChallenge : Not Applicable
- 2) Irritation in both elbows in the upper part (skin irritation) as if it were a rash (Skin irritation - 10040880, Skin irritation - 10040880 )
  - Causality as per reporter : Not assessed
  - Causality as per Mfr : Not assessed
  - DeChallenge : Not applicable
  - ReChallenge : Not Applicable
- 3) He feels his right hand asleep (Numbness in hand - 10049681, Hypoaesthesia - 10020937 )
  - Causality as per reporter : Related
  - Causality as per Mfr : Not assessed
  - DeChallenge : Not applicable
  - ReChallenge : Not Applicable
- 4) Hot flashes he feels in both feet and in the body (Hot flashes - 10020407, Hot flush - 10060800 )
  - Causality as per reporter : Not assessed
  - Causality as per Mfr : Not assessed
  - DeChallenge : Not applicable
  - ReChallenge : Not Applicable
- 5) Fall (Fall - 10016173, Fall - 10016173 )
  - Causality as per reporter : Related
  - Causality as per Mfr : Not assessed
  - DeChallenge : Not applicable
  - ReChallenge : Not Applicable
- 6) Pains that still bother him in the rib (Rib pain - 10048722, Musculoskeletal chest pain - 10050819 )
  - Causality as per reporter : Not assessed
  - Causality as per Mfr : Not assessed
  - DeChallenge : Not applicable
  - ReChallenge : Not Applicable
- 7) Pains that still bother him in the shoulder (Shoulder pain - 10040617, Arthralgia - 10003239 )
  - Causality as per reporter : Related
  - Causality as per Mfr : Not assessed
  - DeChallenge : Not applicable
  - ReChallenge : Not Applicable
- 8) Wear and tear on the right knee when flexing the knee (Knee injury - 10049032, Joint injury - 10060820 )
  - Causality as per reporter : Not assessed
  - Causality as per Mfr : Not assessed
- 9) Patient took 40 mg xtandi daily/Underdosing (Underdose - 10057362, Underdose - 10057362 )
  - 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) UNK UNK, unknown freq.
- 2) 45 mg, every 6 months ongoing
- 3) UNK UNK, unknown freq.

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

Study # :Enzalutamide\_Astellas PSP