17. INDICATION(S) FOR USE 11 Prostate cancer [10060862 - Prostate cancer] 18. THERAPY DATE(S) (from/to) 11 (31/Mar/2023 - UNK)  III. CONCOMITANT DRUG(S) AND HISTORY  22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction) 1)Amlodipine(AMLODIPINE)  Cont  23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergies, pregnancy with last month of period, etc.) 1) PROSTATE CANCER (10060862, Prostate cancer) (Continuing: Yes)  Cont  IV. MANUFACTURER INFORMATION  24a. NAME AND ADDRESS OF MANUFACTURER Name : Tolmar, Inc 701 Centre Avenue Fort Collins, CO, 80526, UNITED STATES OF AMERICA debbie.maierhofer@tolmar.comand+1-4129158447  24a. REPORT NULLIFIED  24b. MFR CONTROL NO.  PA-Tolmar-TLM-2025-01201  24c. DATE RECEIVED BY MANUFACTURER STUDY LITERATURE HEALTH PROFESSIONAL  DATE OF THIS REPORT  25a. REPORT TYPE																				
1. PATIENT INITIALS 1a. COUNTRY P.R.  1. PATIENT INITIALS 1a. COUNTRY D. Down Morth	sus	PECT ADVERSI	E REACTION	ON REPOR	RT															
I. PATENT INITIALS   1a. COUNTRY   2 DATE OF BIRTH   2a. AGE   3. SEX   4-0 REACTION CONSET   5-12 CHECK ALL   18   3   1937	PA-Tolmar-TLM-202	25-01201																		
I. PATENT INITIALS   1a. COUNTRY   2 DATE OF BIRTH   2a. AGE   3. SEX   4-0 REACTION CONSET   5-12 CHECK ALL   18   3   1937					I. REAC	TION	INFOR	MATION												
P.R. PANAMA Day Month Year 88 B Male Day Month Year TO ADVERSE REACTION(S) (Including relevant testafilia data) 1) Cassation of therapy by the healthcare professional (Therapy cessation by healthcare provider (10072906), Therapy cessation for therapy by the healthcare professional (Therapy cessation by healthcare provider (10072906), Therapy cessation for therapy by the healthcare professional (Therapy cessation by healthcare provider (10072906), Therapy cessation for the provider (10072906	1. PATIENT INITIALS 1a. COUNTRY 2. DATE OF BIRTH 2a. AG					GE						-		8-						
7-13 DESCRIBE REACTION(S) (including relevant bestallab data) 1) Cessation of therapy by the healthcare professional (Therapy cessation by healthcare provider (10072906), Therapy cessation of therapy by the healthcare professional (Therapy cessation by healthcare provider (10072906), Therapy cessation of therapy by the healthcare professional (Therapy cessation by healthcare provider (10072906), Therapy cessation of therapy by the healthcare professional (Therapy cessation by healthcare provider (10072906), Therapy cessation of the provider (10072906), Therapy cessation of (10		PANAMA Day Month Year				1		Male	Day Month Year				ear		A T R	APPRO O AD REACT	OPRIA VERS TION	TE E		
1) Cessation of therapy by the healthcare professional (Therapy cessation to by healthcare provider (10072906). Therapy cessation (10085141) Unknown 2) clidn't feel like doing anything (Depressed mood (10012374)). Pepressed mood (10012374) Not Recovered/Not Resolvet/Ongoing 3) All of of weakness (Weakness (10047862). Asthenia (10003549)) Not Recovered/Not Resolvet/Ongoing 3) All of weakness (Weakness (10047862). Asthenia (10003549)) Not Recovered/Not Resolvet/Ongoing 3) All of weakness (Weakness (10047862). Asthenia (10003549)) 14. SUSPECT DRUG(S)InnCude generic name) 19. Eligard'87 (Leuprolide acetate, Leuprolide acetate) (Suspect) (Injection)(Unknown) (Unknown) 10. Eligard'87 (Leuprolide acetate, Leuprolide acetate) (Suspect) (Injection)(Unknown) (Unknown) 11. Subject DRUG(S)InnCude generic name) 12. Journal of the provider of the provider acetate, Leuprolide acetate) (Suspect) (Injection)(Unknown) (Unknown) 13. Subject and the provider acetate, Leuprolide acetate) (Suspect) (Injection)(Unknown) (Unknown) 14. Subject DRUG(S)InnCude generic name) 15. Dally DOSE(S) 16. BAILY DOSE(S) 17. In BOLATIONS (S) (Lauprolide acetate) (Suspect) (Injection)(Unknown) (Unknown) 18. THERAPY LORGE (S) (Lauprolide acetate) (Suspect) (Injection)(Unknown) (Unknown) 19. Subject and the provider acetate (Suspect) (Injection)(Unknown) (Unknown) 19. Subject and the provider acetate (Suspect) (Injection)(Unknown) (Unknown) 19. Subject acetate (Suspect) (Injection)(Unknown) (Unknown) 19. Subject acetate (Suspect) (Injection)(Unknown) (Unknown) (	7+13 DESCRIBE REA	CTION(S) (includii													$\dashv$	٦,	PATIFN	IT DIFI	<b>.</b>	
2 didn't feel like doing anything (Depressed mood (10012374))   Depressed mood (10012374)   Depression management mood mood (10012374)   Depression management mood (10012374)   Depression management mood (10012374)   Depression management mood (10012374)   Depression management mood (10012374)   Depression mood (			hcare prof	essional (T	herapy cess	sation	by hea	Ithcare pr	ovider (	100	72906	6), Tł	nera	ру						IG
Not Recovered/Not Resolved/Ongoing  3) A lot of weakers (Washness (10487682), Asthenia (10003549)) Not Recovered/Not Resolved/Ongoing  Cont.    Grain   Grain	Unknown	•	nressed m	ood (1001)	2374) Denr	ressed	l mood	(1001237	4))							F	PROLO	NGED	INP	
Not Recovered/Not Resolved/Ongoing    Cont.	Not Recovered/N	Not Resolved/On	going	•	,	00000	moou	(1001207	•,,,							7 F	RESUL	TS IN		
OTHER MEDICALLY   REPORTANT CONDITION														Cont	┆	_ [	DISABI	LITY/IN		
II. SUSPECT DRUG(S)(Include generic name) 1) Eligard® (Leuprolide acetate, Leuprolide acetate) (Suspect) (Injection)(Unknown)  Cont.    15. DAILY DOSE(S)   16. ROUTE(S) OF ADMINISTRATION   19. Subcutaneous   27. DID EVENT REAPPEAR REINTROUCTION   21. DID EVENT REAPPEAR REINTROUCTION   22. DID EVENT REAPPEAR REINTROUCTION   23. Subcutaneous   24. DID EVENT REAPPEAR REINTROUCTION   24. NAME AND ADDRESS OF MANUFACTURER NAme: Tolmar, Inc PA-Tolmar-TLM-2025-01201   24c, MFR CONTROL NO. Subject Id :    24. REPORT NULLIFIED														Con	·  _  -					
14. SUSPECT DRUG(S)(include generic name)   1) Eligard® (Leuprolide acetate, Leuprolide acetate) (Suspect) (Injection)(Unknown) (Unknown)   20.																				
1) Eligard® (Leuprolide acetate, Leuprolide acetate) (Suspect) (Injection)(Unknown)  Cont.    ABATE ATTER STOPPINE DRUG?   Ves	14 CHERECT DRUCE	C)/include generie	nama)	II	. SUSPECT	r DRU	G(S)IN	FORMAT	ION						Ioo		ND EV	/ENIT		
15. DAILY DOSE(S) 1) (45 milligram(s), 1 in 6 Month) 2) (45 milligram(s), 1 in 6 Month) 2) (45 milligram(s), 1 in 6 Month) 2) (45 milligram(s), 1 in 6 Month)  17. INDICATION(S) FOR USE 1) Prostate cancer [1060882 - Prostate cancer] 18. THERAPY DATE(S) (from/to) 1) (31/Mar/2023 - UNK)  19. THERAPY DURATION 1) (31/Mar/2023 - UNK)  11. CONCOMITANT DRUG(S) AND HISTORY  22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction) 1) Amilodipine (AML-ODIPINE)  23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergies, pregnancy with last month of period, etc.) 1) PROSTATE CANCER (10060862, Prostate cancer) (Continuing: Yes)  Cont  IV. MANUFACTURER INFORMATION  24a. NAME AND ADDRESS OF MANUFACTURER Name : Tolmar, Inc 701 Centre Avenue Fort Collins, CO, 80526, UNITED STATES OF AMERICA debbie malerhofer@tolmar.comand+1-4129158447  24. REPORT NULLIFIED  24. REPORT NULLIFIED  24. REPORT SOURCE BY MANUFACTURER BY MANUFACTURER 24. REPORT SOURCE BY MANUFACTURER 25. REPORT TYPE  11. DID EVENT AFTER AFTER REPAPY AFTER REPAPY AFTER REPAPY AFTER REPAPY AFTER REPAPY AFTER AFTER REPAPY AFTER AFTER REPAPY AFTER AFTER REPAPY AFTER AFTER AFTER REPAPY AFTER	,	, ,	,	etate) (Sus	pect) (Inject	tion)(U	Inknow	n)(Unknov	vn)					Cont		A S	BATE	AFTI PING I		
1) (45 milligram(s), 1 in 6 Month) 2) (45 milligram(s), 1 in 6 Month) 2) (35 milligram(s), 1 in 6 Month) 2) (31 milligram(s), 1 in 6 Month) 2) (32 milligram(s), 1 in 6 Month) 2) (33 milligram(s), 1 in 6 Month) 2) (34 milligram(s), 1 in 6 Month) 2) (35 milligram(s), 1 in 6 Month) 2) (36 milligram(s), 1 in 6 Month) 2) (37 milligram(s), 1 in 6 Month) 2) (38 milligram(s), 1 in 6 Month) 2) (38 milligram(s), 1 in 6 Month) 2) (38 milligram(s), 1 in 6 Month) 2) (48 milligram(s), 1 in 6 Month) 2) (48 milligram(s), 1 in 6 Month) 2) (48 milligram(s), 1 in 6 Month) 2) (49 milligram(s), 1 in 6 Month) 2) (49 milligram(s), 1 in 6 Month) 2) (40 milligram(s), 1 in 6 month) 2) (41 milligram(s), 1 in 6 month) 2) (42 milligram(s), 1 in 6 month) 2) (43 milligram(s), 1 in 6 month) 2) (44 milligram(s), 1 in 6 month) 2) (45 milligram(s), 1 in 6 month) 2) (45 milligram(s), 1 in 6 month) 2) (46 milligram(s), 1 in 6 month) 2) (47 milligram(s), 1 in 6 month) 2) (48 milligram	15. DAILY DOSE(S) 16. I					16. ROL	ROUTE(S) OF ADMINISTRATION						21.	D	DID EV	/ENT	0	LL NA		
22. (45 milligram(s), 1 in 6 Month)  17. INDICATION(S) FOR USE 1) Prostate cancer [1060862 - Prostate cancer]  18. THERAPY DATE(S) (from/to) 1) (31/Mar/2023 - UNK)  III. CONCOMITANT DRUG(S) AND HISTORY  22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction) 1)Amilodipine(AML-ODIPINE)  23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergies, pregnancy with last month of period, etc.) 1) PROSTATE CANCER (10060862, Prostate cancer) (Continuing: Yes)  Cont  IV. MANUFACTURER INFORMATION  24a. NAME AND ADDRESS OF MANUFACTURER Name: Tolmar, Inc Vanue and Address of Admerica Study Name: NA EudraCT Number: Protocol No: NA Center No.: Subject Id:  24a. REPORT NULLIFIED  24b. MFR CONTROL NO.  PA-Tolmar-TLM-2025-01201  24c. DATE RECEIVED BY MANUFACTURER 28/Apr/2025  DATE OF THIS REPORT  25a. REPORT TYPE	1) (45 milligram(s),	1 in 6 Month)					,	,								R	REAPF	PEAR	ICTI	ON
17. INDICATION(S) FOR USE 1) Prostate cancer [10060862 - Prostate cancer] 18. THERAPY DATE(S) (fromto) 1) (31/Mar/2023 - UNK)  III. CONCOMITANT DRUG(S) AND HISTORY  22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction) 1)Amlodipine(AMLODIPINE)  Cont  23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergies, pregnancy with last month of period, etc.) 1) PROSTATE CANCER (10060862, Prostate cancer) (Continuing: Yes)  Cont  IV. MANUFACTURER INFORMATION  24a. NAME AND ADDRESS OF MANUFACTURER Name : Tolmar, Inc 701 Centre Avenue Fort Collins, CO, 80526, UNITED STATES OF AMERICA debbie.maierhofer@tolmar.comand+1-4129158447  24. REPORT NULLIFIED  YES NO PA-Tolmar-TLM-2025-01201  24c. DATE RECEIVED BY MANUFACTURER STUDY LITERATURE HEALTH PROFESSIONAL  DATE OF THIS REPORT  25a. REPORT TYPE	2) (45 milligram(s), 1 in 6 Month)					2) Subi	, contain to the											0		
18. THERAPY DATE(S) (from/to) 1) (31/Mar/2023 - UNK)  III. CONCOMITANT DRUG(S) AND HISTORY  22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction) 1)Amlodipine(AMLODIPINE)  Cont  23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergies, pregnancy with last month of period, etc.) 1) PROSTATE CANCER (10060862, Prostate cancer) (Continuing: Yes)  Cont  IV. MANUFACTURER INFORMATION  24a. NAME AND ADDRESS OF MANUFACTURER Name: Tolmar, Inc 701 Centre Avenue Fort Collins, CO, 80526, UNITED STATES OF AMERICA debbie.maierhofer@tolmar.comand+1-4129158447  Center No.: Subject Id:  24.REPORT NULLIFIED 24b. MFR CONTROL NO. PA-Tolmar-TLM-2025-01201 24c. DATE RECEIVED BY MANUFACTURER STUDY LITERATURE HEALTH PROFESSIONAL  DATE OF THIS REPORT 25a. REPORT TYPE	. ,														(	NA	: Not	Appl	icab	ole)
1) (31/Mar/2023 - UNK)  III. CONCOMITANT DRUG(S) AND HISTORY  22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)  1)Amlodipine(AMLODIPINE)  Cont  23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)  1) PROSTATE CANCER (10060862, Prostate cancer) (Continuing: Yes)  Cont  IV. MANUFACTURER INFORMATION  24a. NAME AND ADDRESS OF MANUFACTURER Name : Tolmar, Inc  701 Centre Avenue  Fort Collins, CO, 80526, UNITED STATES OF AMERICA debbie.maierhofer@tolmar.comand+1-4129158447  Center No.: Subject Id:  24. REPORT NULLIFIED  24b. MFR CONTROL NO.  PA-Tolmar-TLM-2025-01201  24c. DATE RECEIVED BY MANUFACTURER  25 TUDY LITERATURE HEALTH PROFESSIONAL  DATE OF THIS REPORT  25a. REPORT TYPE	,								-											
22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)  1)Amlodipine(AMLODIPINE)  Cont  23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)  1) PROSTATE CANCER (10060862, Prostate cancer) (Continuing: Yes)  Cont  IV. MANUFACTURER INFORMATION  Study Information  Study Name: NA  EudraCT Number:  Protocol No.: NA  Center No.:  Subject Id:  24b. MFR CONTROL NO.  PA-Tolmar-TLM-2025-01201  24c. DATE RECEIVED BY MANUFACTURER PALTIPEPORT  25a. REPORT TYPE	1																			
1)Amlodipine(AMLODIPINE)  23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergies, pregnancy with last month of period, etc.) 1) PROSTATE CANCER (10060862, Prostate cancer) (Continuing: Yes)    V. MANUFACTURER INFORMATION				III. C	ONCOMITA	ANT D	RUG(S	) AND HIS	STORY											
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		. ,	ES OF ADM	IINISTRATIO	ON (exclude t	hose u	sed to tr	eat reactior	٦)											
1) PROSTATE CANCER (10060862, Prostate cancer) (Continuing: Yes)  Cont  IV. MANUFACTURER INFORMATION  24a. NAME AND ADDRESS OF MANUFACTURER Name : Tolmar, Inc 701 Centre Avenue Fort Collins, CO, 80526, UNITED STATES OF AMERICA debbie.maierhofer@tolmar.comand+1-4129158447  24. REPORT NULLIFIED  24b. MFR CONTROL NO.  YES  NO  PA-Tolmar-TLM-2025-01201  24c. DATE RECEIVED BY MANUFACTURER  25a. REPORT TYPE  25a. REPORT TYPE	T) who dipine (vivile	יטוי וועבי																		Cont
IV. MANUFACTURER INFORMATION  24a. NAME AND ADDRESS OF MANUFACTURER Name : Tolmar, Inc 701 Centre Avenue Fort Collins, CO, 80526, UNITED STATES OF AMERICA debbie.maierhofer@tolmar.comand+1-4129158447  24. REPORT NULLIFIED  24b. MFR CONTROL NO.  PA-Tolmar-TLM-2025-01201  24c. DATE RECEIVED BY MANUFACTURER  28/Apr/2025  DATE OF THIS REPORT  25a. REPORT TYPE			-				onth of p	eriod, etc.)												
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  24.REPORT NULLIFIED 24b. MFR CONTROL NO.  YES NO PA-Tolmar-TLM-2025-01201  24c. DATE RECEIVED BY MANUFACTURER 28/Apr/2025  DATE OF THIS REPORT  25a. REPORT TYPE																				Cont
Name : Tolmar, Inc 701 Centre Avenue Fort Collins, CO, 80526, UNITED STATES OF AMERICA debbie.maierhofer@tolmar.comand+1-4129158447  24b. MFR CONTROL NO.  24c. DATE RECEIVED BY MANUFACTURER  28/Apr/2025  DATE OF THIS REPORT  25a. REPORT TYPE  Study Name: NA EudraCT Number: Protocol No.: NA Center No.: Subject Id :  24d. REPORT SOURCE STUDY LITERATURE HEALTH PROFESSIONAL  DATE OF THIS REPORT  25a. REPORT TYPE				IV	V. MANUFA	ACTUF	RER IN													
701 Centre Avenue Fort Collins, CO, 80526, UNITED STATES OF AMERICA debbie.maierhofer@tolmar.comand+1-4129158447  24.REPORT NULLIFIED 24b. MFR CONTROL NO.  PA-Tolmar-TLM-2025-01201  24c. DATE RECEIVED BY MANUFACTURER 28/Apr/2025  DATE OF THIS REPORT 25a. REPORT TYPE							1 ,													
Fort Collins, CO, 80526, UNITED STATES OF AMERICA debbie.maierhofer@tolmar.comand+1-4129158447  Protocol No.: NA Center No.: Subject Id:  24.REPORT NULLIFIED  24b. MFR CONTROL NO.  PA-Tolmar-TLM-2025-01201  24c. DATE RECEIVED BY MANUFACTURER  28/Apr/2025  DATE OF THIS REPORT  25a. REPORT TYPE	701 Centre Avenue						,													
Center No.: Subject Id:  24.REPORT NULLIFIED  24b. MFR CONTROL NO.  PA-Tolmar-TLM-2025-01201  24c. DATE RECEIVED BY MANUFACTURER  28/Apr/2025  DATE OF THIS REPORT  24b. MFR CONTROL NO.  LITERATURE HEALTH PROFESSIONAL  DATE OF THIS REPORT  25a. REPORT TYPE																				
24.REPORT NULLIFIED  24b. MFR CONTROL NO.  PA-Tolmar-TLM-2025-01201  24c. DATE RECEIVED BY MANUFACTURER  28/Apr/2025  DATE OF THIS REPORT  24b. MFR CONTROL NO.  PA-Tolmar-TLM-2025-01201  24d. REPORT SOURCE  STUDY LITERATURE HEALTH PROFESSIONAL  25a. REPORT TYPE	debble.malemoleræ	gioirriai .comana i	1-412313	JTT1																
PA-Tolmar-TLM-2025-01201  24c. DATE RECEIVED BY MANUFACTURER  28/Apr/2025  DATE OF THIS REPORT  PA-Tolmar-TLM-2025-01201  24d. REPORT SOURCE  STUDY LITERATURE HEALTH PROFESSIONAL  25a. REPORT TYPE	24.REPORT NULLIFIE	ED .	241	o. MFR CON	TROL NO.				Jool Iu	•										
24c. DATE RECEIVED BY MANUFACTURER  28/Apr/2025  DATE OF THIS REPORT  24d. REPORT SOURCE  STUDY LITERATURE HEALTH PROFESSIONAL  25a. REPORT TYPE	YES	NO	PΔ	-Tolmar-Tl	M-2025-01	1201														
28/Apr/2025  DATE OF THIS REPORT  25a. REPORT TYPE						1201														
DATE OF THIS REPORT 25a. REPORT TYPE	STUDY LITERATURE						≣													
	HEALTH PROFESSIONAL																			
	l																			

= Continuation attached sheet(s)..

Mfr. CONTROL NO :PA-Tolmar-TLM-2025-01201

Continuation Sheet for CIOMS report

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

## **Event Description:**

This study report from Panama was received by Adium via Patient Support Program (Reference number: PA-ADIUM-PA-0046-20250428) on 28-Apr-2025 from a consumer (non-healthcare professional) regarding an elderly, 88-year-old male patient who experienced non-serious events of 'a lot of weakness' (asthenia), 'didn't feel like doing anything' (depressed mood), 'Cessation of therapy by the healthcare professional' (therapy cessation) during Eligard (leuprolide acetate) 45 mg therapy for Prostate cancer. The needle component of the constituent device was not identified in the report. The report was sent to Tolmar on 01-May-2025.

The patient's medical history was unknown and current condition included prostate cancer and hypertension.

Concomitant medication included amlodipine.

On 31-Mar-2023, the patient began receiving Eligard 45 mg, every 6 months, via subcutaneous route, for Prostate cancer (Lot numbers and Expiration dates were not provided).

On an unknown date, the patient received Eligard 45 mg, every 6 months, via subcutaneous route, for prostate cancer (Lot numbers and Expiration dates were not provided). He experienced extreme weakness and a lack of desire to do anything that he continued to experience the symptoms but assumed that those aforementioned symptoms were normal because the testosterone hormone kept him agile and energetic. It was his hormone the body needs and gave him motivation, and if it was reduced due to a lack of testosterone.

On 21-Apr-2025, the patient had a testosterone test.

On 22-Apr-2025, the patient went to see the doctor to validate the results, which were 0.05 ng/ml. The doctor told the patient these were the levels he should have and scheduled his next appointment (for 20 or 25-May-2025), to have his testosterone levels checked again and determine whether or not to administer Eligard. The patient mentioned that his testosterone levels were being monitored with blood tests to validate his levels, and based on the results, he was given Eligard.

Corrective treatment was not reported.

Relevant test results included:

On 21-Apr-2025: Testosterone: 0.05 ng/ml (Ref. range not provided)

On an unknown date: Testosterone: Testosterone levels continued to be low (Ref. range not provided)

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

The outcomes of asthenia, depressed mood were not resolved, and therapy cessation was unknown.

The reporter did not assess the seriousness of asthenia, depressed mood and therapy cessation.

The reporter did not provide the causality of asthenia, depressed mood and therapy cessation in relationship to Eligard and Eligard unspecified device.

No follow-up queries were raised.

## Listedness

Therapy cessation >Eligard® >unlisted as per CCDS Eligard® > 7-Nov-2024

Therapy cessation> Eligard® >unlisted as per Canadian Monograph Eligard®> 2-Apr-2025

Therapy cessation> Eligard®>unlisted as per USPI Eligard®>Feb-2025

Therapy cessation> Eligard® Unspecified Device>unlisted as per USPI Eligard®>Feb-2025

Asthenia>Eligard® >listed as per CCDS Eligard®> 7-Nov-2024

Asthenia> Eligard® >listed as per Canadian Monograph Eligard®> 2-Apr-2025

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

Asthenia > Eligard® Unspecified Device > listed as per USPI Eligard® > Feb-2025

Depressed mood >Eligard® >listed as per CCDS Eligard®> 7-Nov-2024

Depressed mood > Eligard® > listed as per Canadian Monograph Eligard® > 2-Apr-2025

Depressed mood > Eligard®>listed as per USPI Eligard®>Feb-2025

Depressed mood > Eligard® Unspecified Device> listed as per USPI Eligard®>Feb-2025

Company Remarks (Sender's Comments):

Evaluator comment (Tolmar): This is regarding an elderly, 88-year-old male patient who experienced asthenia (a lot of weakness), depressed mood (didn't feel like doing anything) and therapy cessation (Cessation of therapy by the healthcare professional) during Eligard (leuprolide acetate) 45 mg therapy for Prostate cancer. Tolmar assessed the reported events as non-serious since they did not meet the ICH seriousness criteria. The causality of events asthenia and depressed mood were assessed as related to suspect drug Eligard(not related to device) considering the known safety profile

## Continuation Sheet for CIOMS report

of the drug, elderly age and prostate cancer could be confounders for the events. The causality of the event therapy cessation was assessed as not related to suspect Eligard(drug and device) as it was a decision made by health care professional in response to the underlying condition and testosterone values.

## Additional Information (Continuation...)

## Lab Result:

Test Name	Test Date	Test Result	Normal Value		
TESTOSTERONE	21/Apr/2025	0.05 nanogram per millliiter			
TESTOSTERONE	Unknown				

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

2) Test Name: TESTOSTERONE

Result Unstructured Data (free text): Testosterone levels continued to be low

Test Date: Unknown

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

Product-Reaction Level

1) Drug : Eligard® (Leuprolide acetate)

Active Substance : 1) Leuprolide acetate

**Drug Characterization** : Suspect Form of Admin : 1) Injection 2) Injection

: 1) Unknown

Lot Number 2) Unknown

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

(45 milligram(s), 1 in 6 Month) Route of Admin : 1) Subcutaneous

2) Subcutaneous

: 1) Prostate cancer [10060862 - Prostate cancer] Indications

; 1) From : 31/Mar/2023 To :Unknown Therapy Dates

Action(s) Taken With Drug Unknown

Causality

Daily Dose

1) Cessation of therapy by the healthcare professional (Therapy cessation by healthcare provider - 10072906, Therapy cessation - 10065154)

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

2) didn't feel like doing anything (Depressed mood - 10012374, Depressed mood - 10012374)

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

3) A lot of weakness (Weakness - 10047862, Asthenia - 10003549)

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

Labeling:

1) Cessation of therapy by the healthcare professional

CORE UnLabeled

2) didn't feel like doing anything

CORE Labeled 3) A lot of weakness

CORE Labeled

2) Drug : Eligard® Unspecified Device (Leuprolide acetate)

Mfr. CONTROL NO :PA-Tolmar-TLM-2025-01201

# Continuation Sheet for CIOMS report

Active Substance : 1) Leuprolide acetate

Drug Characterization : Suspect
Form of Admin : 1) Injection
Lot Number : 1) Unknown

Indications : 1) Prostate cancer [10060862 - Prostate cancer]

Action(s) Taken With Drug : Not applicable

#### Causality

1) Cessation of therapy by the healthcare professional (Therapy cessation by healthcare provider - 10072906, Therapy cessation - 10065154)

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

2) didn't feel like doing anything (Depressed mood - 10012374, Depressed mood - 10012374)

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

3) A lot of weakness (Weakness - 10047862, Asthenia - 10003549)

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

# Labeling:

1) Cessation of therapy by the healthcare professional

CORE

2) didn't feel like doing anything

CORE

3) A lot of weakness

CORE

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

Dosage Text : Drug 1 :Eligard®

1) ELIGARD 45 MG x 1 LIO x 1 JER

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

1). Drug : Amlodipine
Active Substance : 1) AMLODIPINE

Form Strength

Daily Dose : 1) (1 in 1 Day)

Indications : 1) hypertension [10020772 - Hypertension]

# 23. OTHER RELEVANT HISTORY (Continuation...)

2) HYPERTENSION (HIGH BLOOD PRESSURE) (10020772, Hypertension) (Continuing: YES)