SUSPECT ADVERSE REACTION REPORT

PA-Tolmar-TLM-2025-00282

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
R-M	PANAMA	04	Apr	1929	95	Male		Feb	2025

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

1) "stoma" all over the body that itch and burn (Ill-defined disorder (10061520), Ill-defined disorder (10061520)) (/Feb/2025 -) - Recovering/Resolving
2) "stoma" all over the body that itch and burn (Burning skin (10006792), Skin burning sensation (10054786)) (/Feb/2025 -) - Recovering/Resolving
3) Left knee pain/ the pain in his left knee (Knee pain (10023477), Arthralgia (10003239)) (/Jul/2025 -) - Not Recovered/Not Resolved/Ongoing
4) "stoma" all over the body that itch and burn (Itching all over (10023086), Pruritus (10037087)) (/Feb/2025 -) - Recovering/Resolving

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) Eligard® (Leuprolide acetate, Leuprolide acetate) (Suspect) (Injection)(15276CUY;UNK;UNK)

Cont..

15. DAILY DOSE(S)

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

16. ROUTE(S) OF ADMINISTRATION

1) Subcutaneous

17. INDICATION(S) FOR USE

1) Prostate cancer [10060862 - Prostate cancer]

18. THERAPY DATE(S) (from/to)

1) (21/May/2019 - Ongoing)

19. THERAPY DURATION

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

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

(NA : Not Applicable)

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) PROSTATE CANCER (10060862, Prostate cancer) (Continuing: Yes)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER

Name : Tolmar, Inc
701 Centre Avenue
Fort Collins, CO, 80526, UNITED STATES OF AMERICA
Anjan.Chatterjee@tolmar.comand+1--9702124900

Study Information
Study Name: NA
EudraCT Number:
Protocol No.: NA
Center No.:
Subject Id :

24.REPORT NULLIFIED ☐ YES ☐ NO

24b. MFR CONTROL NO.

PA-Tolmar-TLM-2025-00282

24c. DATE RECEIVED BY MANUFACTURER

01/Aug/2025

24d. REPORT SOURCE ☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL

DATE OF THIS REPORT

07/Aug/2025

25a. REPORT TYPE ☐ INITIAL ☑ FOLLOWUP

= Continuation attached sheet(s)..

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 (reference number: PA-ADIUM-PA-0035-20250408) via Patient Support Program on 08-Apr-2025 from a consumer (non-healthcare professional) regarding an elderly 95-year-old male patient who experienced non-serious events of ‘stoma all over the body that itch and burn' ('ill-defined disorder', 'pruritus', 'skin burning sensation') 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 09-Apr-2025.

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

Concomitant medications were unknown.

On 21-May-2019, the patient began receiving Eligard 45 mg, every 6 months, via subcutaneous route for prostate cancer (Lot number: 15276CUY and Expiration dates: Aug-2026).

On an unknown date in Feb-2025, the patient developed stomas all over his body that caused itching and burning. No further details were available.

Corrective treatment was unknown.

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

The outcomes of ill-defined disorder, pruritus and skin burning sensation were recovering.

The reporter did not assess the seriousness of ill-defined disorder, pruritus and skin burning sensation.

The reporter did not provide the causality of ill-defined disorder, pruritus, skin burning sensation in relationship to Eligard and Eligard Unspecified Device.

No follow-up queries raised.

On 01-Aug-2025, follow-up information was received by Adium via Patient Support Program “Asofarma a tu Lado” (reference number: PA-ADIUM-PA-0035-20250408 (1)) from a consumer (non-healthcare professional) and sent to Tolmar on 04-Aug-2025. New information included: added a new non-serious event of "left knee pain/ the pain in his left knee" (Arthralgia).

On an unknown date, in Jul-2025 the patient had pain in his left knee. No further details were provided.

Corrective treatment was unknown.

Action taken with Eligard in response to the event was dose not changed. De-challenge and re-challenge were not applicable.

The outcome of arthralgia was not resolved.

The reporter did not assess the seriousness of arthralgia.

The reporter did not provide the causality of arthralgia in relationship to Eligard and Eligard unspecified device.

No further information is expected as consent to be contacted was not provided.

Listedness

Ill-defined disorder>Eligard>Unlisted as per CCDS>07-Nov-2024
Ill-defined disorder>Eligard>Unlisted as per USPI>Feb-2025
Ill-defined disorder>Eligard unspecified device>Unlisted as per USPI>Feb-2025
Ill-defined disorder>Eligard>Unlisted as per Canadian monograph>02-Apr-2025

Skin burning sensation>Eligard>Unlisted as per CCDS>07-Nov-2024
Skin burning sensation>Eligard>Unlisted as per USPI>Feb-2025
Skin burning sensation>Eligard unspecified device>Unlisted as per USPI>Feb-2025
Skin burning sensation>Eligard>Unlisted as per Canadian monograph>02-Apr-2025

Pruritus>Eligard>Listed as per CCDS>07-Nov-2024
Pruritus>Eligard>Listed as per USPI>Feb-2025
Pruritus>Eligard unspecified device>Listed as per USPI>Feb-2025
Pruritus>Eligard>Listed as per Canadian monograph>02-Apr-2025

Arthralgia>Eligard>Listed as per CCDS>07-Nov-2024

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Arthralgia>Eligard>Listed as per USPI>Feb-2025
Arthralgia>Eligard unspecified device>Listed as per USPI>Feb-2025
Arthralgia>Eligard>Listed as per Canadian monograph>02-Apr-2025

Company Remarks (Sender's Comments) :

Evaluator comment (Tolmar): This is regarding an elderly 95-year-old male patient who experienced non-serious events of ill-defined disorder, pruritus, skin burning sensation (‘stoma all over the body that itch and burn'), during Eligard (leuprolide acetate) 45 mg therapy for prostate cancer. Tolmar assessed the events as non-serious since it does not meet the ICH seriousness criteria and is not an IME event. Tolmar assessed the causality of the events as not related to Eligard (drug and device) considering the nature of reported events and the inconsistency of the events with the product safety profile.

FU-Event arthralgia (Knee pain) added. Tolmar assessed the events as non-serious since it does not meet the ICH seriousness criteria and is not an IME event. Tolmar assessed the causality of the event arthralgia as related to Eligard (drug) based on the known safety profile of the drug and not related to device. However, the event maybe attributed to elderly age. Causality of the events ill-defined disorder, pruritus, skin burning sensation is retained as per previous assessment.

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
Lot Number	:	1) 15276CUY;UNK;UNK
Daily Dose	:	(45 milligram(s), 1 in 6 Month)
Route of Admin	:	1) Subcutaneous
Indications	:	1) Prostate cancer [10060862 - Prostate cancer]
Therapy Dates	:	1) From : 21/May/2019 To :Continuing
Action(s) Taken With Drug	:	Dose not changed

Causality

1) "stoma" all over the body that itch and burn (Ill-defined disorder - 10061520, Ill-defined disorder - 10061520)

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

2) "stoma" all over the body that itch and burn (Burning skin - 10006792, Skin burning sensation - 10054786)

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

3) Left knee pain/ the pain in his left knee (Knee pain - 10023477, Arthralgia - 10003239)

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

4) "stoma" all over the body that itch and burn (Itching all over - 10023086, Pruritus - 10037087)

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

Labeling :

1) "stoma" all over the body that itch and burn	
CORE	UnLabeled
2) "stoma" all over the body that itch and burn	
CORE	UnLabeled
3) Left knee pain/ the pain in his left knee	
CORE	Labeled
4) "stoma" all over the body that itch and burn	
CORE	Labeled

2) Drug	:	Eligard® Unspecified Device (Leuprolide acetate)
Active Substance	:	1) Leuprolide acetate

Continuation Sheet for CIOMS report

Drug Characterization	:	Suspect
Form of Admin	:	1) Injection
Lot Number	:	1) 15276CUY;UNK;UNK
Indications	:	1) Prostate cancer [10060862 - Prostate cancer]
Action(s) Taken With Drug	:	Not applicable

Causality

1) "stoma" all over the body that itch and burn (Ill-defined disorder - 10061520, Ill-defined disorder - 10061520)

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

2) "stoma" all over the body that itch and burn (Burning skin - 10006792, Skin burning sensation - 10054786)

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

3) Left knee pain/ the pain in his left knee (Knee pain - 10023477, Arthralgia - 10003239)

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

4) "stoma" all over the body that itch and burn (Itching all over - 10023086, Pruritus - 10037087)

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

Labeling :

1) "stoma" all over the body that itch and burn
   CORE
2) "stoma" all over the body that itch and burn
   CORE
3) Left knee pain/ the pain in his left knee
   CORE
4) "stoma" all over the body that itch and burn
   CORE

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

Dosage Text :

Drug 1 :Eligard®

1) ELIGARD 45 MG x 1 LIO x 1 JER Injection, powder, lyophilized, for suspension