SUSPECT ADVERSE REACTION REPORT

DO-Tolmar-TLM-2025-04108

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year	Years		Day	Month	Year	
WRMG	DOMINICAN Cont..	05	May	1973	52	Male	08	Mar	2025	

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

1) Sexual impotence (Impotence (10021550), Erectile dysfunction (10061461))
(08/Mar/2025 -) - Recovering/Resolving
2) "Coldness immediately after my hot flashes" (Coldness (10009871), Feeling cold (10016326))
(08/Mar/2025 -) - Not Recovered/Not Resolved/Ongoing
3) Hot flashes (Hot flashes (10020407), Hot flush (10060800))
(08/Mar/2025 -) - Not Recovered/Not Resolved/Ongoing

- ☐ 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)(Unknown)

Cont..

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
1) (45 milligram(s), 1 in 6 Month)	1) Subcutaneous

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

(NA : Not Applicable)

17. INDICATION(S) FOR USE

1) Product used for unknown indication [10070592 - Product used for unknown indication]

18. THERAPY DATE(S) (from/to)	19. THERAPY DURATION
1) (03/Mar/2025 -)	

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.)

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	24b. MFR CONTROL NO.
☐ YES ☐ NO	DO-Tolmar-TLM-2025-04108
24c. DATE RECEIVED BY MANUFACTURER: 24/Jun/2025	24d. REPORT SOURCE: ☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT: 01/Jul/2025	25a. REPORT TYPE: ☑ INITIAL ☐ FOLLOWUP

= Continuation attached sheet(s)..

Continuation Sheet for CIOMS report

1a. COUNTRY

DOMINICAN REPUBLIC

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

Event Description :

This study report from Dominican Republic was received by Adium via Patient Support Programme (Reference number: DO-ADIUM-DO-0060-20250624) on 24-Jun-2025 from a reporter (consumer or non-healthcare professional) regarding an adult, 52-year-old male patient who experienced a serious (medically significant) event of ‘‘Sexual impotence" (erectile dysfunction) and non-serious events "Hot flashes" (hot flush) and "Coldness immediately after my hot flashes" (feeling cold) during Eligard (leuprolide acetate) 45 mg therapy for unknown indication. The needle component of the constituent device was not identified in the report. The report was sent to Tolmar on 25-Jun-2025.

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

Concomitant medication was unknown.

On 03-Mar2025, the patient began receiving Eligard 45 mg every 6 months, via subcutaneous route, for unknown indication (Lot numbers and Expiration dates were not provided).

On 08-Mar-2025, patient had impotence which improved but his hot flashes and cold flashes persist every 4 hours, intensity was moderated but those were uncomfortable. No further details were provided.

Corrective treatment was not reported.

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

The outcome of feeling hot and feeling cold was not resolved whereas of erectile dysfunction was recovering.

The reporter did not assess the seriousness of erectile dysfunction, feeling hot and feeling cold.

The reporter provided the causality of erectile dysfunction, feeling hot and feeling cold in relationship to Eligard and Eligard unspecified device as related.

No further queries raised.

Listedness
Erectile dysfunction >Eligard® >unlisted as per CCDS Eligard®> 7-Nov-2024
Erectile dysfunction> Eligard® >unlisted as per Canadian Monograph Eligard®> 2-Apr-2025
Erectile dysfunction> Eligard®>unlisted as per USPI Eligard®>Feb-2025
Erectile dysfunction> Eligard® Unspecified Device>unlisted as per USPI Eligard®>Feb-2025

Feeling cold >Eligard® >unlisted as per CCDS Eligard®> 7-Nov-2024
Feeling cold > Eligard® >unlisted as per Canadian Monograph Eligard®> 2-Apr-2025
Feeling cold > Eligard®>unlisted as per USPI Eligard®>Feb-2025
Feeling cold > Eligard® Unspecified Device>unlisted as per USPI Eligard®>Feb-2025

Hot flush>Eligard® >listed as per CCDS Eligard®> 7-Nov-2024
Hot flush> Eligard® >listed as per Canadian Monograph Eligard®> 2-Apr-2025
Hot flush> Eligard®>listed as per USPI Eligard®>Feb-2025
Hot flush> Eligard® Unspecified Device> listed as per USPI Eligard®>Feb-2025

Company Remarks (Sender's Comments) :

Evaluator comment (Tolmar): This is regarding an adult, 52-year-old male patient who experienced erectile dysfunction (Sexual impotence), hot flush (Hot flashes) and feeling cold (Coldness immediately after my hot flashes) during Eligard (leuprolide acetate) 45 mg therapy for unknown indication. Tolmar assessed event erectile dysfunction was assessed as serious as it is included in IME list and remaining events were assessed as non-serious since they did not meet the ICH seriousness criteria. Based on close temporality the causal role of suspect drug (Eligard) with the events erectile dysfunction, hot flush and feeling cold cannot be ruled out. The events were assessed as not related to device component of Eligard.

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

Product-Reaction Level

1) Drug : Eligard® (Leuprolide acetate)

Continuation Sheet for CIOMS report

Active Substance : 1) Leuprolide acetate
Drug Characterization : Suspect
Form of Admin : 1) Injection
Lot Number : 1) Unknown
Daily Dose : (45 milligram(s), 1 in 6 Month)
Route of Admin : 1) Subcutaneous
Indications : 1) Product used for unknown indication [10070592 - Product used for unknown indication]
Therapy Dates : 1) From : 03/Mar/2025 To :Unknown
Action(s) Taken With Drug : Unknown

Causality

1) Sexual impotence (Impotence - 10021550, Erectile dysfunction - 10061461)
Causality as per reporter : Related
Causality as per Mfr : Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
2) "Coldness immediately after my hot flashes" (Coldness - 10009871, Feeling cold - 10016326)
Causality as per reporter : Related
Causality as per Mfr : Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
3) Hot flashes (Hot flashes - 10020407, Hot flush - 10060800)
Causality as per reporter : Related
Causality as per Mfr : Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) Sexual impotence
CORE UnLabeled
2) "Coldness immediately after my hot flashes"
CORE UnLabeled
3) Hot flashes
CORE Labeled

2) Drug : Eligard® Unspecified Device (Leuprolide acetate)
Active Substance : 1) Leuprolide acetate
Drug Characterization : Suspect
Form of Admin : 1) Injection
Lot Number : 1) Unknown
Indications : 1) Product used for unknown indication [10070592 - Product used for unknown indication]
Action(s) Taken With Drug : Not applicable

Causality

1) Sexual impotence (Impotence - 10021550, Erectile dysfunction - 10061461)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
2) "Coldness immediately after my hot flashes" (Coldness - 10009871, Feeling cold - 10016326)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
3) Hot flashes (Hot flashes - 10020407, Hot flush - 10060800)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) Sexual impotence
CORE
2) "Coldness immediately after my hot flashes"
CORE
3) Hot flashes
CORE

Continuation Sheet for CIOMS report