SUSPECT ADVERSE REACTION REPORT

SV-Tolmar-TLM-2025-04918

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	
L-R	EL Cont..					Female	22	Jul	2025	

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

1) Off-label use for breast cancer indication (Off label use (10053762), Off label use (10053762)) (22/Jul/2025 -) - Unknown

- ☐ 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) (22.5 Milligram, Injection)(15274CUY; UNK; UNK) Cont..

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

15. DAILY DOSE(S)

1) (22.5 milligram(s), 1 in 3 Month)

16. ROUTE(S) OF ADMINISTRATION

1) Subcutaneous

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

(NA : Not Applicable)

17. INDICATION(S) FOR USE

1) Breast cancer [10006187 - Breast cancer]

18. THERAPY DATE(S) (from/to)	19. THERAPY DURATION
1) (22/Jul/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.)

1) BREAST CANCER (10006187, Breast 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	24b. MFR CONTROL NO.
☐ YES ☐ NO	SV-Tolmar-TLM-2025-04918
24c. DATE RECEIVED BY MANUFACTURER: 22/Jul/2025	24d. REPORT SOURCE: ☑ STUDY ☐ LITERATURE ☑ HEALTH PROFESSIONAL
DATE OF THIS REPORT: 25/Jul/2025	25a. REPORT TYPE: ☑ INITIAL ☐ FOLLOWUP

= Continuation attached sheet(s)..

Continuation Sheet for CIOMS report

1a. COUNTRY

EL SALVADOR

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

Event Description :

This study report from El Salvador was received by Adium via the Patient Support Program "ASOFARMA A TU LADO"(reference number: SV-ADIUM-SV-0016-20250722) on 22-Jul-2025 from other health professional regarding a female patient of unknown age who experienced a non-serious event of ''off-label use for breast cancer indication" (off label use) during Eligard (Leuprolide acetate) 22.5 mg therapy for the indication of breast cancer. The needle component of the constituent device was not identified in the report. The report was sent to Tolmar on 23-Jul-2025.

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

Concomitant medications were unknown.

On 22-Jul-2025, the patient received Eligard 22.5 mg, every 3 months, via subcutaneous route for the indication of breast cancer (Lot number: 15274CUY; UNK; UNK and Expiration dates: Aug-2026; UNK; UNK). No further information was provided.

Correction treatment was unknown.

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

The outcome of off label use was unknown.

The reporter did not assess the seriousness of off label use.

The reporter assessed the causality of inappropriate schedule of product administration in relationship to Eligard and Eligard unspecified device as not related.

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

Listedness

Off label use>Eligard>Unlisted as per CCDS>07-Nov-2024
Off label use>Eligard>Unlisted as per USPI>Feb-2025
Off label use>Eligard unspecified device>Unlisted as per USPI>Feb-2025
Off label use>Eligard>Unlisted as per Canadian monograph>02-Apr-2025

Company Remarks (Sender's Comments) :

Evaluator comment (Tolmar): This is regarding a female patient who had off label use ('Off-label use for breast cancer indication') during Eligard (leuprolide acetate) 22.5 mg therapy for breast cancer. Tolmar assessed the event as non-serious since it does not meet the ICH seriousness criteria and is not an IME event. The reported event off label use was assessed as not related to Eligard (drug and device) as it is attributed to prescribing physician.

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

Product-Reaction Level

1) Drug	:	Eligard® (Leuprolide acetate)
Active Substance	:	1) Leuprolide acetate
Drug Characterization	:	Suspect
Form Strength	:	1) 22.5 Milligram
Form of Admin	:	1) Injection
Lot Number	:	1) 15274CUY; UNK; UNK
Daily Dose	:	(22.5 milligram(s), 1 in 3 Month)
Route of Admin	:	1) Subcutaneous
Indications	:	1) Breast cancer [10006187 - Breast cancer]
Therapy Dates	:	1) From : 22/Jul/2025 To :Unknown
Action(s) Taken With Drug	:	Unknown

Causality

1) Off-label use for breast cancer indication (Off label use - 10053762, Off label use - 10053762)

Causality as per reporter	:	Not Related

Continuation Sheet for CIOMS report

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

Labeling :

1) Off-label use for breast cancer indication
CORE UnLabeled

2) Drug	: Eligard® Unspecified Device (Leuprolide acetate)
Active Substance	: 1) Leuprolide acetate
Drug Characterization	: Suspect
Form of Admin	: 1) Injection
Lot Number	: 1) 15274CUY; UNK; UNK
Indications	: 1) Breast cancer [10006187 - Breast cancer]
Action(s) Taken With Drug	: Not applicable

Causality

1) Off-label use for breast cancer indication (Off label use - 10053762, Off label use - 10053762)

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

Labeling :

1) Off-label use for breast cancer indication
CORE