CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

NI-Tolmar-TLM-2025-04396

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	4-6 REACTION ONSET		
		Day	Month	Year	Years		Day	Month	Year
NEMO	NICARAGUA	08	Aug	2016	8	Female		Jun	2025

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

1) Outbreak of pimples on the face similar to blackheads (Pimple (10035048), Acne (10000496)) (/Jun/2025 -) - Not Recovered/Not Resolved/Ongoing

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) (22.5 Milligram, Injection)(Unknown)

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) Drug use for unknown indication [10057097 - Drug use for unknown indication]

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

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	NI-Tolmar-TLM-2025-04396
24c. DATE RECEIVED BY MANUFACTURER: 03/Jul/2025	24d. REPORT SOURCE: ☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT: 09/Jul/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 Nicaragua was received by Adium via ‘ASOFARMA A TU LADO' via Patient Support Program (reference number: NI-ADIUM-NI-0054-20250703) on 03-Jul-2025 from a consumer (non-health care professional) regarding a child 08-year-old female patient who experienced a non-serious event of "outbreak of pimples on the face similar to blackheads " (Acne) during Eligard (leuprolide acetate) 22.5 mg therapy for an unknown indication. The report was sent to Tolmar on 04-Jul-2025.

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

Concomitant medications were unknown.

On 03-Apr-2025, the patient began receiving Eligard 22.5 mg, every 3 months via subcutaneous route for an unknown indication (Lot numbers and Expiration dates were not provided).

On an unknown date in Jun-2025, the patient experienced outbreak of pimples on the face similar to blackheads. No further details were available.

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 Acne was not recovered.

The reporter did not assess the seriousness of Acne.

The reporter assessed the causality of Acne in relationship to Eligard and Eligard Unspecified device as related.

No follow-up queries raised.

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

Company Remarks (Sender's Comments) :

Evaluator comment (Tolmar): This is regarding a child 08-year-old female patient who experienced Acne (outbreak of pimples on the face similar to blackheads) during Eligard (leuprolide acetate) 22.5 mg therapy for an unknown indication. Tolmar assessed the reported event as non-serious since it did not meet the ICH seriousness criteria. The causality of event acne was assessed as not related to suspect Eligard(drug and device) considering the nature of event, etiology and inconsistency with the safety profile of the drug.

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) Unknown
Daily Dose	:	(22.5 milligram(s), 1 in 3 Month)
Route of Admin	:	1) Subcutaneous
Indications	:	1) Drug use for unknown indication [10057097 - Drug use for unknown indication]
Therapy Dates	:	1) From : 03/Apr/2025 To :Continuing
Action(s) Taken With Drug	:	Dose not changed

Causality

1) Outbreak of pimples on the face similar to blackheads (Pimple - 10035048, Acne - 10000496)

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

Labeling :

Continuation Sheet for CIOMS report

1) Outbreak of pimples on the face similar to blackheads
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) Unknown
Indications : 1) Drug use for unknown indication [10057097 - Drug use for unknown indication]
Action(s) Taken With Drug : Not applicable

Causality

1) Outbreak of pimples on the face similar to blackheads (Pimple - 10035048, Acne - 10000496)
Causality as per reporter : Related
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) Outbreak of pimples on the face similar to blackheads
CORE