SUSPECT ADVERSE REACTION REPORT

HN-Tolmar-TLM-2025-02462

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
PRIVACY	HONDURAS	26	Oct	2015	9	Female			

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

1) Acne Vulgaris Pre-adolescent (Acne vulgaris (10000519), Acne (10000496))
Recovered/Resolved

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) (45 Milligram, Injection)(L15276CUY; UNK; UNK)

Cont..

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

15. DAILY DOSE(S)

1) (45 milligram(s), 1 in 6 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) precocious puberty [10058084 - Precocious puberty]

18. THERAPY DATE(S) (from/to)	19. THERAPY DURATION
(- 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.)

1) PRECOCIOUS PUBERTY (10058084, Precocious puberty) (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
debbie.maierhofer@tolmar.comand+1-4129158447

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

24.REPORT NULLIFIED	24b. MFR CONTROL NO.
☐ YES ☐ NO	HN-Tolmar-TLM-2025-02462
24c. DATE RECEIVED BY MANUFACTURER: 26/May/2025	24d. REPORT SOURCE: ☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT: 05/Jun/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 Honduras was received by Adium via patient support program (Asofarma A Tu Lado) (reference number: HN-ADIUM-HN-0219-20250526) on 26-May-2025, from a consumer (non-healthcare professional) regarding an child-09-year-old female patient who experienced a non-serious event of ‘acne Vulgaris pre-adolescent' (acne) during Eligard (leuprolide acetate) 45 mg therapy for precocious puberty. The needle component of the constituent device was not identified in the report. The report was sent to Tolmar on 27-May-2025.

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

Concomitant medications were unknown.

On an unknown date the patient began receiving Eligard 45 mg every 6 months via subcutaneous route for precocious puberty (lot numbers: L15276CUY; UNK; UNK and expiration date: -Aug-2026).

On an unknown date the patient experienced pre-adolescent acne vulgaris as she started with small bumps located on the forehead and to that the treating physician suggested to seek a dermatologist-pediatrician. No further details were provided. Severity of event was reported as mild.

Corrective treatment was unknown.

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

The outcome of acne was resolved.

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 further information is expected as the reporter does not consent to be contacted for follow up.

Listedness

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

Company Remarks (Sender's Comments) :

Evaluator comment (Tolmar): This is regarding a child 09-year-old female patient who had Acne (Acne Vulgaris Pre-adolescent), during Eligard (leuprolide acetate) 45 mg therapy for precocious puberty. 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 acne was assessed as not related to Eligard (drug and device) considering the nature of the reported event and known 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) 45 Milligram
Form of Admin	:	1) Injection
Lot Number	:	1) L15276CUY; UNK; UNK
Daily Dose	:	(45 milligram(s), 1 in 6 Month)
Route of Admin	:	1) Subcutaneous
Indications	:	1) precocious puberty [10058084 - Precocious puberty]
Action(s) Taken With Drug	:	Dose not changed

Causality

1) Acne Vulgaris Pre-adolescent (Acne vulgaris - 10000519, Acne - 10000496)

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

Continuation Sheet for CIOMS report

Labeling :

1) Acne Vulgaris Pre-adolescent
CORE UnLabeled

2) Drug : Eligard (Leuprolide acetate)
Active Substance : 1) Leuprolide acetate
Drug Characterization : Suspect
Lot Number : 1) L15276CUY; UNK; UNK
Indications : 1) precocious puberty [10058084 - Precocious puberty]
Action(s) Taken With Drug : Not applicable

Causality

1) Acne Vulgaris Pre-adolescent (Acne vulgaris - 10000519, Acne - 10000496)
Causality as per reporter : Related
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) Acne Vulgaris Pre-adolescent
CORE