SUSPECT ADVERSE REACTION REPORT

HN-Tolmar-TLM-2025-01405

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE Years	3. SEX	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year			Day	Month	Year	
ARPH	HONDURAS	22	Feb	2016	9	Female		Feb	2025	

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

1) Headache (Headache (10019211), Headache (10019211))
(/Feb/2025 -) - Recovered/Resolved
2) Weight gain (Weight gain (10047896), Weight increased (10047899))
Not Recovered/Not Resolved/Ongoing

Cont..

- ☐ 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) Precocious Puberty [10058084 - Precocious puberty]

18. THERAPY DATE(S) (from/to)	19. THERAPY DURATION
1) (18/Jul/2024 - 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-2025-01405
24c. DATE RECEIVED BY MANUFACTURER: 06/May/2025	24d. REPORT SOURCE: ☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT: 17/May/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 (reference number: HN-ADIUM-HN-0189-20250506) on 06-May-2025 from a consumer (Non-healthcare professional) regarding a child of 09-Year-old Female patient who experienced “Headache" (Headache), and "Weight gain" (Weight increased) 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 07-May-2025.

The patient's medical history was unknown and current conditions included precocious puberty.

Concomitant medications were unknown.

On 18-Jul-2024, the patient began receiving Eligard 45 milligram, every 24 weeks, via subcutaneous route for precocious puberty (Lot number and Expiration date were not reported).

On an unspecified date, the patient had mild weight gain which was observed by her family member in charge during the visit, they also referred that the child had headache in the middle of the day on some occasions for approximately 2 to 3 months, but the pain did not require any medication or medical evaluation. No further information was provided.

Corrective treatment was not reported.

Relevant test results included:
On an unknown date: Weight: gain (Ref. range: Not provided).

Action taken with Eligard in response to the events was Dose Not Changed. De-challenge and re-challenge were Not applicable.

The outcome of headache was recovered and weight increased was not recovered.

The reporter did not assess the seriousness of headache and weight increased.

The reporter assessed the causality of headache and weight increased in relationship to Eligard and Eligard unspecified device as related.

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

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

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

Company Remarks (Sender's Comments) :

Evaluator comment (Tolmar): This is regarding a child of 9-year-old female patient who experienced Headache (Headache), and Weight increased (Weight gain) during Eligard (Leuprolide acetate) 45 mg therapy for precocious puberty. Tolmar assessed the reported events as non-serious since they did not meet the ICH seriousness criteria. The causality of events weight increased, and headache were assessed as related to suspect drug Eligard(not related to device) considering the known safety profile of the drug, age group could also be confounder for the event.

Additional Information (Continuation...)

Test Result (Code) / Result Unstructured Data (free text) :

1) Test Name: WEIGHT

Result Unstructured Data (free text) : weight gain
Test Date:

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

Product-Reaction Level

1) Drug	:	Eligard® (Leuprolide acetate)
Active Substance	:	1) Leuprolide acetate

Continuation Sheet for CIOMS report

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) Precocious Puberty [10058084 - Precocious puberty]
Therapy Dates	:	1) From : 18/Jul/2024 To :Continuing
Action(s) Taken With Drug	:	Dose not changed

Causality

1) Headache (Headache - 10019211, Headache - 10019211)

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

2) Weight gain (Weight gain - 10047896, Weight increased - 10047899)

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

Labeling :

1) Headache
CORE Labeled
2) Weight gain
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) Precocious Puberty [10058084 - Precocious puberty]
Action(s) Taken With Drug	:	Not applicable

Causality

1) Headache (Headache - 10019211, Headache - 10019211)

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

2) Weight gain (Weight gain - 10047896, Weight increased - 10047899)

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

Labeling :

1) Headache
CORE
2) Weight gain
CORE