

SUSPECT ADVERSE REACTION REPORT NI-Tolmar-TLM-2025-05930												

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) TLVG	1a. COUNTRY NICARAGUA	2. DATE OF BIRTH			2a. AGE Years 9	3. SEX Female	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION <input type="checkbox"/> PATIENT DIED <input type="checkbox"/> LIFE THREATENING <input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION <input type="checkbox"/> RESULTS IN PERSISTENCE OR SIGNIFICANT DISABILITY/INCAPACITY <input type="checkbox"/> CONGENITAL ANOMALY <input type="checkbox"/> OTHER MEDICALLY IMPORTANT CONDITION
		Day 11	Month Aug	Year 2016			Day	Month Apr	Year 2025	
7+13 DESCRIBE REACTION(S) (including relevant tests/lab data) 1) Leg cramps (Leg cramps (10024125), Muscle spasms (10028334)) (/Apr/2025 -) - Not Recovered/Not Resolved/Ongoing										

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? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> 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 <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA (NA : Not Applicable)
17. INDICATION(S) FOR USE 1) Central Precocious Puberty [10073186 - Central precocious puberty]			
18. THERAPY DATE(S) (from/to) 1) (03/Mar/2025 - ongoing)	19. THERAPY DURATION		

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) CENTRAL PRECOCIOUS PUBERTY (10073186, Central 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 Anjan.Chatterjee@tolmar.comand+1-9702124900		Study Information Study Name: NA EudraCT Number: Protocol No.: NA Center No.: Subject Id :	
24. REPORT NULLIFIED <input type="checkbox"/> YES <input type="checkbox"/> NO	24b. MFR CONTROL NO. NI-Tolmar-TLM-2025-05930		
24c. DATE RECEIVED BY MANUFACTURER 18/Aug/2025	24d. REPORT SOURCE <input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL		
DATE OF THIS REPORT 21/Aug/2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> 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 Patient Support Program (reference number: NI-ADIUM-NI-0067-20250818 (0)) on 18-Aug-2025 from a consumer (non-healthcare professional) regarding a child, 9-year-old female patient who experienced a non-serious event of 'Leg cramps' (Muscle spasms) 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 19-Aug-2025.

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

Concomitant medications were unknown.

On 03-Mar-2025, the patient began receiving Eligard 45 mg, every 6 months via subcutaneous route for precocious puberty (Lot numbers and Expiration dates were not provided).

On an unknown date in Apr-2025, the patient experienced leg cramps. No further details were available.

Corrective treatment was not reported.

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

The outcome of muscle spasms was not recovered.

The reporter assessed the seriousness of muscle spasms as non-serious.

The reporter assessed the causality of muscle spasms in relationship to Eligard and Eligard unspecified device as not related.

No further queries were raised.

Listedness

Muscle spasms>Eligard>Listed as per CCDS>07-Nov-2024

Muscle spasms>Eligard>Unlisted as per USPI>Feb-2025

Muscle spasms>Eligard unspecified device>Unlisted as per USPI>Feb-2025

Muscle spasms>Eligard>Listed 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 Muscle spasms (Leg cramps), 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 muscle spasms assessed as not related to Eligard (drug and device) based on the etio-pathology of the event, and inconsistency with drug properties.

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

Product-Reaction Level

1) Drug	: Eligard® (Leuprolide acetate)
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) Central Precocious Puberty [10073186 - Central precocious puberty]
Therapy Dates	: 1) From : 03/Mar/2025 To : Continuing
Action(s) Taken With Drug	: Dose not changed

Causality

1) Leg cramps (Leg cramps - 10024125, Muscle spasms - 10028334)	
Causality as per reporter	: Not Related
Causality as per Mfr	: Not Related
DeChallenge	: Not applicable
ReChallenge	: Not Applicable

Labeling :

Continuation Sheet for CIOMS report

1) Leg cramps
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) Central Precocious Puberty [10073186 - Central precocious puberty]
Action(s) Taken With Drug : Not applicable

Causality

1) Leg cramps (Leg cramps - 10024125, Muscle spasms - 10028334)
Causality as per reporter : Not Related
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) Leg cramps
CORE