SUSPECT ADVERSE REACTION REPORT

PA-Tolmar-TLM-2025-01893

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE Years	3. SEX	4-6 REACTION ONSET		
		Day	Month	Year			Day	Month	Year
ACSC	PANAMA	24	Oct	2015	9	Female	05	May	2025

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

1) Pain below the belly button radiating to the pelvis (Lower abdominal pain (10024940), Abdominal pain lower (10000084)) (05/May/2025 -) - Unknown
2) Pain below the belly button radiating to the pelvis (Pelvic pain (10034263), Pelvic pain (10034263)) (05/May/2025 -) - Unknown
3) Pain below the belly button radiating to the pelvis (Radiating pain (10078920), Pain (10033371)) (05/May/2025 -) - Unknown

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) (Injection)(15022CUY; 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) Unknown

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

(NA : Not Applicable)

17. INDICATION(S) FOR USE

1) Central precocious puberty [10073186 - Central precocious puberty]

18. THERAPY DATE(S) (from/to)	19. THERAPY DURATION
1) (23/Aug/2024 -)	

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) (23/Aug/2024 -) (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	PA-Tolmar-TLM-2025-01893
24c. DATE RECEIVED BY MANUFACTURER: 15/May/2025	24d. REPORT SOURCE: ☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT: 23/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 Panama was received by Adium via two electronic forms through the Jazz Safety tool of the "ASOFARMA A TU LADO" Patient Support Program (reference number: PA-ADIUM-PA-0050-2025051) on 15-May-2025 from consumer (non-healthcare professional) regarding a 9-year-old female child patient who experienced non-serious events of ‘‘Pain below the belly button radiating to the pelvis" (Abdominal pain lower), "Pain below the belly button radiating to the pelvis" (Pelvic pain) and "Pain below the belly button radiating to the pelvis" (Pain) during Eligard (Leuprolide acetate) 45mg therapy for Central precocious puberty. The needle component of the constituent device was not identified in the report. The report was sent to Tolmar on 16-May-2025.

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

Concomitant medications were unknown.

On 23-Aug-2024, the patient began receiving Eligard 45 mg every 6 Months via unknown route of administration for Central precocious puberty (Lot numbers: 15022CUY; Unk; Unk and Expiration dates: 01Aug2026; Unk; Unk).

On 05-May-2025, the patient experienced pain below the belly button radiating to the pelvis. No further details were provided.

Corrective treatment was not reported.

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

The outcome of abdominal pain lower, pelvic pain and pain was unknown.

The reporter did not assess the seriousness of abdominal pain lower, pelvic pain and pain.

The reporter assessed the causality of pelvic pain in relationship to Eligard and Eligard unspecified device as related.

The reporter did not provide the causality of abdominal pain lower and pain in relationship to Eligard and Eligard unspecified device.

No further queries were raised.

Abdominal pain lower>Eligard>Unlisted as per CCDS>07-Nov-2024
Abdominal pain lower>Eligard>Unlisted as per USPI>Feb-2025
Abdominal pain lower>Eligard Terumo Needle Pre-connected Syringe>Unlisted as per USPI>Feb-2025
Abdominal pain lower>Eligard>Unlisted as per Canadian monograph>02-Apr-2025

Pelvic pain>Eligard>Unlisted as per CCDS>07-Nov-2024
Pelvic pain>Eligard>Unlisted as per USPI>Feb-2025
Pelvic pain>Eligard Terumo Needle Pre-connected Syringe>Unlisted as per USPI>Feb-2025
Pelvic pain>Eligard>Unlisted as per Canadian monograph>02-Apr-2025

Pain>Eligard>Unlisted as per CCDS>07-Nov-2024
Pain>Eligard>Unlisted as per USPI>Feb-2025
Pain>Eligard Terumo Needle Pre-connected Syringe>Unlisted as per USPI>Feb-2025
Pain>Eligard>Unlisted as per Canadian monograph>02-Apr-2025

Company Remarks (Sender's Comments) :

Evaluator's comment: As per company conventions, the events Abdominal pain lower (Pain below the belly button radiating to the pelvis) and Pelvic pain (Pain below the belly button radiating to the pelvis) and Pain (Pain below the belly button radiating to the pelvis) are considered with not applicable causality by default. The events are unlisted/unexpected with reference to the USPI and as per company conventions. The benefit-risk profile of Eligard is not adversely affected by this report.

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) 15022CUY; Unk; Unk
Daily Dose	: (45 milligram(s), 1 in 6 Month)

Continuation Sheet for CIOMS report

Route of Admin : 1) Unknown
Indications : 1) Central precocious puberty [10073186 - Central precocious puberty]
Therapy Dates : 1) From : 23/Aug/2024 To :Unknown
Action(s) Taken With Drug : Unknown

Causality

1) Pain below the belly button radiating to the pelvis (Lower abdominal pain - 10024940, Abdominal pain lower - 10000084)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
2) Pain below the belly button radiating to the pelvis (Pelvic pain - 10034263, Pelvic pain - 10034263)
Causality as per reporter : Related
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
3) Pain below the belly button radiating to the pelvis (Radiating pain - 10078920, Pain - 10033371)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) Pain below the belly button radiating to the pelvis
CORE UnLabeled
2) Pain below the belly button radiating to the pelvis
CORE UnLabeled
3) Pain below the belly button radiating to the pelvis
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) 15022CUY; Unk; Unk
Indications : 1) Central precocious puberty [10073186 - Central precocious puberty]
Action(s) Taken With Drug : Not applicable

Causality

1) Pain below the belly button radiating to the pelvis (Lower abdominal pain - 10024940, Abdominal pain lower - 10000084)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
2) Pain below the belly button radiating to the pelvis (Pelvic pain - 10034263, Pelvic pain - 10034263)
Causality as per reporter : Related
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
3) Pain below the belly button radiating to the pelvis (Radiating pain - 10078920, Pain - 10033371)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) Pain below the belly button radiating to the pelvis
CORE UnLabeled
2) Pain below the belly button radiating to the pelvis
CORE UnLabeled
3) Pain below the belly button radiating to the pelvis
CORE UnLabeled