SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET		
		Day	Month	Year				Day	Month	Year
MIHL	HONDURAS	10	AUG	2016	8 Years	Female	Unk	27	FEB	2025

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas)

her 'waist' hurts, the pain is on both sides and radiates down the lumbar area [Pelvic pain]
skin allergy in the form of hives [Hives]
Bone pain [Bone pain]
Indurated abscess in the left buttock / the surrounding area is hardened / Inflammatory changes / Slightly red color [Injection site abscess]
skin allergy in the form of itching [Itching]
Severe headache [Headache]

Case Description: This Study report from HONDURAS was received by

(Continued on Additional Information Page)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
- ☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING
- ☐ CONGENITAL ANOMALY
- ☐ OTHER

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) Eligard® (Leuprolide acetate) Injection, 45 milligram {Lot # 15109CUY; Exp.Dt. MAR-2026}
#2) Eligard® Unspecified Device (Leuprolide acetate) Injection {Lot # **(Continued on Additional Information Page)**

20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☒ NA

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 45 milligram, q 6 month	#1) Subcutaneous use
#2) UNK	#2) Unknown

17. INDICATION(S) FOR USE
#1) Precocious Puberty (Precocious puberty)
#2) Precocious Puberty (Precocious puberty)

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☒ NA

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 19-FEB-2025 / Ongoing	#1) Unknown
#2) Unknown	#2) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) OMEGA 3 [FISH OIL] (FISH OIL) ; Unknown
#2) DIGLET (COLECALCIFEROL) ; Unknown

23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	Precocious puberty (Precocious puberty)
Unknown	Allergy	Food allergy (Food allergy)
	Lactose, nuts	

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
Tolmar, Inc.
Laura Pethick, PharmD
701 Centre Ave
Fort Collins, CO 80526 UNITED STATES

26. REMARKS

24b. MFR CONTROL NO.
25HN057313

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.

24c. DATE RECEIVED BY MANUFACTURER
26-MAR-2025

24d. REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL ☒ OTHER: Study

DATE OF THIS REPORT
01-APR-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 2

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Adium via Asofarma a tu lado Patient Support Program (reference number: HN-ADIUM-HN-0086-20250228) on 28-FEB-2025 from a Consumer/Other Non-Health Prof regarding a Child 8 Years old Female patient who experienced Indurated abscess in the left buttock / the surrounding area is hardened / Inflammatory changes / Slightly red color (Injection site abscess), during Eligard (Leuprolide acetate) 45 milligram therapy for Precocious puberty. The needle component of the constituent device was not identified in the report. The report was sent to Tolmar on 03-MAR-2025.

The patient's medical history and current conditions included Precocious puberty, Food allergy.

Concomitant medications included OMEGA 3 and OTHER THERAPEUTIC PRODUCTS.

On 25-AUG-2023, the patient began receiving Eligard 45 milligram, q 6 month via Subcutaneous use for Precocious puberty (Lot numbers and Expiration dates not provided). On 19-FEB-2025, the patient received Eligard 45 milligram, q 6 month via Subcutaneous use (Lot number: 15109CUY; Expiration date: MAR-2016). On 27-FEB-2025, 6 fays after the most recent dose of Eligard, the patient experienced burning, redness and hardening at injection site. She was taken to a private hospital, an hemogram was attached and the indication for medication was given, which was applied at the time. The evaluation of the doctor concluded that it was an indurated abscess in the left buttock, but that the medication was applied in the left upper quadrant and it was not seen as an application error. On an unknown date, the person in charge of the program made an in-person follow-up visit to assess the affected area, the physical examination showed hardening in the left upper quadrant, a measurement was taken and it was observed that it was within the insertion area, there were inflammatory changes, slightly red color in the area, no temperature elevation was palpated, but the surrounding area was hardened. No fever was reported. She continued oral antibiotic therapy. Corrective treatment included ceftriaxone, cefalexin and acetaminophen.

Relevant test results included:
27-FEB-2025 : Granulocyte count: 53 (Ref range: Not provided)
27-FEB-2025 : Haematocrit: 39.5 % percent (Ref range: Not provided)
27-FEB-2025: Haemoglobin: 12.3 gram per decilitre (Ref range: Not provided)
27-FEB-2025 : Lymphocyte count: 35 (Ref range: Not provided)
27-FEB-2025 : Mean cell haemoglobin: 26.7 picogram (Ref range: Not provided)
27-FEB-2025 : Mean cell haemoglobin concentration: 31.1 gram per decilitre (Ref range: Not provided)
27-FEB-2025 : Mean cell volume : 85.7 (Ref range: Not provided)
27-FEB-2025: MID: 12 (Ref range: Not provided)
27-FEB-2025 : Red blood cell count: 4.61 cubic millimetre (Ref range: Not provided)
27-FEB-2025 : White blood cell count: 13,000 cubic millimetre (Ref range: Not provided)
27-FEB-2025 : Platelet count: 241,000 cubic millimetre (Ref range: Not provided)
On an unknown date: Body temperature: No fever (Ref range: Not provided)

Action taken with Eligard in response to the event was Dose Not Changed. De-challenge and re-challenge were Not applicable. The outcome of Injection site abscess was Unknown.

The reporter did not assess the seriousness or causality of the event in relationship to Eligard.

On 19-MAR-2025, follow-up information was received by Adium Patient support program (reference number: HN-ADIUM-HN-0086-20250228) from a Consumer/Other Non-Health Prof and sent to Tolmar on 20-MAR-2025. New information included: Added new event of her waist hurts, the pain was on both sides and radiates down the lumbar area (Pelvic pain) and clinical details of event Injection site abscess, updated event outcome of event Injection site abscess from Unknown to Recovered/Resolved.

On an unspecified date, at an unknown time after the most recent dose of Eligard, the patient experienced her waist hurts and that on Friday patient's mother would take her to the laboratory for a General Urine Test, as she hopes that it was not a urinary tract infection, as the pain was on both sides and radiates down the lumbar area. As per reported, there was no longer any sign of infection at the application site, area without redness, no hardening. Action taken with Eligard in response to the events was Dose Not Changed. De-challenge and re-challenge were Not applicable. The outcome of Injection site abscess was Recovered/Resolved. The outcome of Pelvic pain was Unknown.

The reporter did not assess the seriousness or causality of the events in relationship to Eligard.

On 26-MAR-2025, follow-up information was received by Adium Patient support program (reference number: HN-ADIUM-HN-0086-20250228) from a Consumer/Other Non-Health Prof and sent to Tolmar on 27-MAR-2025. New information included: Added new non-serious events of bone pain (Bone pain), skin allergy in the form of itching (itching), skin allergy in the form of hives (hives), Severe headache (headache).

On an unknown date, two weeks prior to this report in 2025, the patient developed two episodes of severe headache. On 25-MAR-2025, the patient developed Bone pain, skin allergy (hives and itching). On an unknown date patient underwent urine examination with unknown result. Action taken with Eligard in response to the events was Dose Not Changed. De-challenge and re-challenge were Not applicable. The outcome of Bone pain was Unknown. The outcome of hives was Not Recovered/Not Resolved.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The outcome of itching was Not Recovered/Not Resolved. The outcome of headache was Not Recovered/Not Resolved.

The reporter did not assess the seriousness or causality of the events in relationship to Eligard.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Body temperature No fever		
2	27-FEB-2025	Granulocyte count 53, Units and Reference range not provided		
3	27-FEB-2025	Haematocrit Reference range not provided	39.5 % percent	
4	27-FEB-2025	Haemoglobin Reference range not provided	12.3 gram per decilitre	
5	27-FEB-2025	Lymphocyte count 35, Units and Reference range not provided		
6	27-FEB-2025	Mean cell haemoglobin Reference range not provided	26.7 picogram	
7	27-FEB-2025	Mean cell haemoglobin concentration Reference range not provided	31.1 gram per decilitre	
8	27-FEB-2025	Mean cell volume 85.7, Units and Reference range not provided		
9	27-FEB-2025	Platelet count Reference range not provided	241,000 cubic millimetre	
10	27-FEB-2025	Red blood cell count Reference range not provided	4.61 cubic millimetre	
11		Urine analysis Unknown result		
12	27-FEB-2025	White blood cell count Reference range not provided	13,000 cubic millimetre	

Mfr. Control Number: 25HN057313

ADDITIONAL INFORMATION

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#1) Eligard® (Leuprolide acetate) Injection, 45 milligram; Regimen #2	45 milligram, q 6 month; Subcutaneous use	Precocious Puberty (Precocious puberty)	25-AUG-2023 / Ongoing; Unknown
#2) Eligard® Unspecified Device (Leuprolide acetate) Injection {Lot # 15109CUY}; Regimen #1	UNK; Unknown	Precocious Puberty (Precocious puberty)	Unknown; Unknown