CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

HN-TOLMAR, INC.-25HN057313

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	
MIHL	HONDURAS	10	Aug	2016	8	Female			2025	

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

1) HER 'WAIST' HURTS, THE PAIN IS ON BOTH SIDES AND RADIATES DOWN THE LUMBAR AREA (Pelvic pain (10034263), Pelvic pain (10034263))
Unknown
2) SKIN ALLERGY IN THE FORM OF ITCHING (Itching (10023084), Pruritus (10037087))
(25/Mar/2025 -) - Not Recovered/Not Resolved/Ongoing
3) BONE PAIN (Bone pain (10006002), Bone pain (10006002))
(25/Mar/2025 -) - Unknown
4) INDURATED ABSCESS IN THE LEFT BUTTOCK / THE SURROUNDING AREA IS HARDENED / INFLAMMATORY CHANGES / SLIGHTLY RED COLOR (Injection site abscess (10022044), Injection site abscess (10022044))
(27/Feb/2025 -) - Recovered/Resolved

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)(15109CUY)(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
2) (45 milligram(s), 1 in 6 Month)	2) 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
(19-Feb-2025 - Ongoing)	

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

1)DIGLET(COLECALCIFEROL)

Cont..

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

1) PRECOCIOUS PUBERTY (10058084, Precocious puberty) (Continuing: Yes)

Cont..

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	24b. MFR CONTROL NO.
☐ YES ☐ NO	HN-TOLMAR, INC.-25HN057313
24c. DATE RECEIVED BY MANUFACTURER	24d. REPORT SOURCE
08/Jul/2025	☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT	25a. REPORT TYPE
19/Jul/2025	☐ INITIAL ☑ FOLLOWUP

= Continuation attached sheet(s)..

Continuation Sheet for CIOMS report

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

5) SKIN ALLERGY IN THE FORM OF HIVES (Hives (10020197), Urticaria (10046735)(25/Mar/2025 -) - Not Recovered/Not Resolved/Ongoing)

6) SEVERE HEADACHE/she has had mild episodes of headache (Headache (10019211), Headache (10019211)(//2025 -) - Recovered/Resolved)

7) pain in her feet (Foot pain (10016974), Pain in extremity (10033425) - Recovered/Resolved)

8) Fever (Fever (10016558), Pyrexia (10037660)(27/Feb/2025 - /Mar/2025) - Recovered/Resolved)

9) Pain at the application site (Application site pain (10003051), Application site pain (10003051)(27/Feb/2025 - /Mar/2025) - Recovered/Resolved)

10) Infection at the application site (Injection site infection (10022076), Injection site infection (10022076)(27/Feb/2025 - /Mar/2025) - Recovered/Resolved)

11) Suspension of medication (Therapy cessation (10065154), Therapy cessation (10065154)(08/Feb/2025 -) - Unknown)

Event Description :

This Study report from HONDURAS was received by 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. 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.

On 23-May-2025, follow-up information was received by Adium via Asofarma a tu lado Patient support program (reference number: HN-ADIUM-HN-0086-20250228) from a Consumer (non-healthcare professional) and sent to Tolmar on 26-May-2025. New information included: Added new non-serious event of Foot pain (Pain in extremity) and updated verbatim of “Headache” from ‘severe headache' to “severe headache/she has had mild episodes of headache” and outcome from ‘not recovered' to ‘resolved'.

On an unknown date, the patient experienced mild episodes of headache and pain in her feet, from time to time. No further information was available.

Corrective treatment included Panadol (acetaminophen).

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

The outcome of headache and pain in extremity was resolved

The reporter assessed the seriousness of headache and pain in extremity as non-serious.

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

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

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

On 08-Jul-2025, the follow up was received by Adium via Patient support program (reference number: HN-ADIUM-HN-0086-20250228) from a consumer (patient or family member) (non-healthcare professional) and sent to Tolmar on 09-Jul-2025. New information included: patient demographics (height and weight) were added. New non-serious events of “Fever” (Pyrexia), “Pain at the application site” (Application site pain), “Infection at the application site” (Injection site infection), “Suspension of medication” (Therapy cessation) were added. Concomitants medications were added. Action taken updated from dose not changed to unknown.

Concomitant medications included ceftriaxone and cefalexin.

On 08-Feb-2025, the patient's medication was suspended.

On 27-Feb-2025, the patient experienced severe pain and infection at the application site along with fever. No further information reported.

Corrective treatment included Panadol and antibiotic.

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

On an unknown date in Mar-2025, the outcome of pyrexia, Injection site infection and application site pain was resolved.

The outcome of therapy cessation was unknown.

The reporter did not assess the seriousness of pyrexia and application site pain.

The reporter did not provide the causality of therapy cessation and assessed as related for pyrexia, Injection site infection, application site pain in relationship to Eligard and Eligard unspecified device.

No-follow-up queries raised.

Pelvic pain>Eligard>Unisted as per CCDS>07-Nov-2024
Pelvic pain>Eligard>Unisted as per USPI>Feb-2025

Continuation Sheet for CIOMS report

Pelvic pain>Eligard unspecified device>Unisted as per USPI>Feb-2025
Pelvic pain>Eligard>Unisted as per Canadian monograph>02-Apr-2025

Pruritus>Eligard>Listed as per CCDS>07-Nov-2024
Pruritus>Eligard>Listed as per USPI>Feb-2025
Pruritus>Eligard unspecified device>Listed as per USPI>Feb-2025
Pruritus>Eligard>Unisted as per Canadian monograph>02-Apr-2025

Bone pain>Eligard>Listed as per CCDS>07-Nov-2024
Bone pain>Eligard>Listed as per USPI>Feb-2025
Bone pain>Eligard unspecified device>Listed as per USPI>Feb-2025
Bone pain>Eligard>Listed as per Canadian monograph>02-Apr-2025

Injection site abscess>Eligard>Listed as per CCDS>07-Nov-2024
Injection site abscess>Eligard>Listed as per USPI>Feb-2025
Injection site abscess>Eligard unspecified device>Listed as per USPI>Feb-2025
Injection site abscess>Eligard>Listed as per Canadian monograph>02-Apr-2025

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

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

Pain in extremity>Eligard>Listed as per CCDS>07-Nov-2024
Pain in extremity>Eligard>Listed as per USPI>Feb-2025
Pain in extremity>Eligard unspecified device>Listed as per USPI>Feb-2025
Pain in extremity>Eligard>Listed as per Canadian monograph>02-Apr-2025

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

Injection site pain>Eligard>Listed as per CCDS>07-Nov-2024
Injection site pain>Eligard>Listed as per USPI>Feb-2025
Injection site pain>Eligard unspecified device>Listed as per USPI>Feb-2025
Injection site pain>Eligard>Unlisted as per Canadian monograph>02-Apr-2025

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

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

Company Remarks (Sender's Comments) :

Evaluator comment (Tolmar): This case is regarding a child, 8 years old female patient who experienced injection site abscess (indurated abscess in the left buttock / the surrounding area is hardened / inflammatory changes / slightly red color), pelvic pain (her waist hurts, the pain was on both sides and radiates down the lumbar area), bone pain (bone pain), pruritus and urticaria (skin allergy in the form of itching and hives), severe headache (headache), pain in extremity (foot pain), during Eligard (leuprolide acetate) 45 milligram therapy for precocious puberty. Tolmar assessed the reported events as non-serious since they did not meet the ICH seriousness criteria and are not IME events. The causality for the events injection site abscess, headache and pain in extremity were assessed as related with Eligard (drug) considering implied temporality and known safety profile of the drug. Underlying precocious puberty can be a risk factor. The causality for the events pelvic pain and bone pain were assessed as not related to Eligard (drug) as they can be alternatively explained by patient's underlying precocious puberty which can lead to these events. Pruritus and itching can be explained by patient's underlying allergies and due to incompatible temporality for allergic reactions, their causality is not related with Eligard (drug). The reported events were assessed as not related to device component of Eligard.

Continuation Sheet for CIOMS report

FU events added were pyrexia, Injection site infection, application site pain and therapy cessation. Tolmar assessed the reported events as non-serious since they did not meet the ICH seriousness criteria and are not IME events. The causality for the events pyrexia and Injection site infection were assessed as related with Eligard (drug) considering implied temporality and known safety profile of the drug and not related to device. Event of injection site pain was assessed as related to Elifard (drug and device) based on temporality and nature of event. Event therapy cessation was assessed as not related to Eligard (drug and device) as it is due to human actions.

Additional Information (Continuation...)

Lab Result :

Test Name	Test Date	Test Result	Normal Value
BODY TEMPERATURE	Unknown		
ERYTHROCYTES	27/Feb/2025	4.61 cubic millimetre	
GRANULOCYTES	27/Feb/2025		
HEMATOCRIT	27/Feb/2025	39.5 % percent	
HEMOGLOBIN	27/Feb/2025	12.3 gram per decilitre	
LEUKOCYTES	27/Feb/2025		
LYMPHOCYTES	27/Feb/2025		
MCH	27/Feb/2025	26.7 picogram	
MCHC	27/Feb/2025	31.1 gram per decilitre	
MCV	27/Feb/2025		
PLATELETS	27/Feb/2025		
URINE EXAMINATION	Unknown		

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

1) Test Name: BODY TEMPERATURE

Result Unstructured Data (free text) : No fever

Test Date: Unknown

3) Test Name: GRANULOCYTES

Result Unstructured Data (free text) : 53, Units and Reference range not provided

Test Date: 27/Feb/2025

6) Test Name: LEUKOCYTES

Result Unstructured Data (free text) : Test Result:13,000 mm3;Reference range not provided

Test Date: 27/Feb/2025

7) Test Name: LYMPHOCYTES

Result Unstructured Data (free text) : 35, Units and Reference range not provided

Test Date: 27/Feb/2025

10) Test Name: MCV

Result Unstructured Data (free text) : 85.7, Units and Reference range not provided

Test Date: 27/Feb/2025

11) Test Name: PLATELETS

Result Unstructured Data (free text) : Test Result:241,000 mm3;Reference range not provided

Test Date: 27/Feb/2025

Continuation Sheet for CIOMS report

12) Test Name: URINE EXAMINATION
Result Unstructured Data (free text) : Unknown result
Test Date: Unknown
Lab Comments :

1) Test Name : BODY TEMPERATURE
Lab Comments : No fever
2) Test Name : ERYTHROCYTES
Lab Comments : Reference range not provided
3) Test Name : GRANULOCYTES
Lab Comments : 53, Units and Reference range not provided
4) Test Name : HEMATOCRIT
Lab Comments : Reference range not provided
5) Test Name : HEMOGLOBIN
Lab Comments : Reference range not provided
6) Test Name : LEUKOCYTES
Lab Comments : Reference range not provided
7) Test Name : LYMPHOCYTES
Lab Comments : 35, Units and Reference range not provided
8) Test Name : MCH
Lab Comments : Reference range not provided
9) Test Name : MCHC
Lab Comments : Reference range not provided
10) Test Name : MCV
Lab Comments : 85.7, Units and Reference range not provided
11) Test Name : PLATELETS
Lab Comments : Reference range not provided
12) Test Name : URINE EXAMINATION
Lab Comments : Unknown result

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 2) Injection
Lot Number	:	1) 15109CUY 2) Unknown
Daily Dose	:	(45 milligram(s), 1 in 6 Month) (45 milligram(s), 1 in 6 Month)
Route of Admin	:	1) Subcutaneous 2) Subcutaneous
Indications	:	1) Precocious Puberty [10058084 - Precocious puberty]
Therapy Dates	:	2) From : 25/Aug/2023 To :Unknown
Action(s) Taken With Drug	:	Unknown

Causality

1) HER ‘WAIST' HURTS, THE PAIN IS ON BOTH SIDES AND RADIATES DOWN THE LUMBAR AREA (Pelvic pain - 10034263, Pelvic pain - 10034263)

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

2) SKIN ALLERGY IN THE FORM OF ITCHING (Itching - 10023084, Pruritus - 10037087)

Causality as per reporter	:	Not Reported
Causality as per Mfr	:	Not Related

Continuation Sheet for CIOMS report

DeChallenge : Not applicable
ReChallenge : Not Applicable

3) BONE PAIN (Bone pain - 10006002, Bone pain - 10006002)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

4) INDURATED ABSCESS IN THE LEFT BUTTOCK / THE SURROUNDING AREA IS HARDENED / INFLAMMATORY CHANGES / SLIGHTLY RED COLOR (Injection site abscess - 10022044, Injection site abscess - 10022044)
Causality as per reporter : Not Reported
Causality as per Mfr : Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

5) SKIN ALLERGY IN THE FORM OF HIVES (Hives - 10020197, Urticaria - 10046735)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

6) SEVERE HEADACHE/she has had mild episodes of headache (Headache - 10019211, Headache - 10019211)
Causality as per reporter : Related
Causality as per Mfr : Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

7) pain in her feet (Foot pain - 10016974, Pain in extremity - 10033425)
Causality as per reporter : Not Related
Causality as per Mfr : Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

8) Fever (Fever - 10016558, Pyrexia - 10037660)
Causality as per reporter : Related
Causality as per Mfr : Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

9) Pain at the application site (Application site pain - 10003051, Application site pain - 10003051)
Causality as per reporter : Related
Causality as per Mfr : Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

10) Infection at the application site (Injection site infection - 10022076, Injection site infection - 10022076)
Causality as per reporter : Related
Causality as per Mfr : Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

11) Suspension of medication (Therapy cessation - 10065154, Therapy cessation - 10065154)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) HER ‘WAIST' HURTS, THE PAIN IS ON BOTH SIDES AND RADIATES DOWN THE LUMBAR AREA
CORE UnLabeled
2) SKIN ALLERGY IN THE FORM OF ITCHING
CORE Labeled
3) BONE PAIN
CORE Labeled
4) INDURATED ABSCESS IN THE LEFT BUTTOCK / THE SURROUNDING AREA IS HARDENED / INFLAMMATORY CHANGES / SLIGHTLY RED COLOR
CORE Labeled
5) SKIN ALLERGY IN THE FORM OF HIVES
CORE Labeled
6) SEVERE HEADACHE/she has had mild episodes of headache
CORE Labeled
7) pain in her feet
CORE Labeled
8) Fever

Continuation Sheet for CIOMS report

CORE	Labeled
9) Pain at the application site	
CORE	Labeled
10) Infection at the application site	
CORE	UnLabeled
11) Suspension of medication	
CORE	UnLabeled

2) Drug	:	Eligard® Unspecified Device (Leuprolide acetate)
Active Substance	:	1) Leuprolide acetate
Drug Characterization	:	Suspect
Form of Admin	:	1) Injection
		2) Injection
Lot Number	:	1) 15109CUY
		2) 15109CUY
Route of Admin	:	1) Subcutaneous
		2) Subcutaneous
Indications	:	1) Precocious Puberty [10058084 - Precocious puberty]
Action(s) Taken With Drug	:	Not applicable

Causality

1) HER 'WAIST' HURTS, THE PAIN IS ON BOTH SIDES AND RADIATES DOWN THE LUMBAR AREA (Pelvic pain - 10034263, Pelvic pain - 10034263)

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

2) SKIN ALLERGY IN THE FORM OF ITCHING (Itching - 10023084, Pruritus - 10037087)

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

3) BONE PAIN (Bone pain - 10006002, Bone pain - 10006002)

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

4) INDURATED ABSCESS IN THE LEFT BUTTOCK / THE SURROUNDING AREA IS HARDENED / INFLAMMATORY CHANGES / SLIGHTLY RED COLOR (Injection site abscess - 10022044, Injection site abscess - 10022044)

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

5) SKIN ALLERGY IN THE FORM OF HIVES (Hives - 10020197, Urticaria - 10046735)

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

6) SEVERE HEADACHE/she has had mild episodes of headache (Headache - 10019211, Headache - 10019211)

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

7) pain in her feet (Foot pain - 10016974, Pain in extremity - 10033425)

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

8) Fever (Fever - 10016558, Pyrexia - 10037660)

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

9) Pain at the application site (Application site pain - 10003051, Application site pain - 10003051)

Causality as per reporter	:	Related
Causality as per Mfr	:	Related

Continuation Sheet for CIOMS report

DeChallenge : Not applicable
ReChallenge : Not Applicable

10) Infection at the application site (Injection site infection - 10022076, Injection site infection - 10022076)
Causality as per reporter : Related
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

11) Suspension of medication (Therapy cessation - 10065154, Therapy cessation - 10065154)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) HER 'WAIST' HURTS, THE PAIN IS ON BOTH SIDES AND RADIATES DOWN THE LUMBAR AREA
CORE
2) SKIN ALLERGY IN THE FORM OF ITCHING
CORE
3) BONE PAIN
CORE
4) INDURATED ABSCESS IN THE LEFT BUTTOCK / THE SURROUNDING AREA IS HARDENED / INFLAMMATORY CHANGES / SLIGHTLY RED COLOR
CORE
5) SKIN ALLERGY IN THE FORM OF HIVES
CORE
6) SEVERE HEADACHE/she has had mild episodes of headache
CORE
7) pain in her feet
CORE
8) Fever
CORE
9) Pain at the application site
CORE
10) Infection at the application site
CORE
11) Suspension of medication
CORE

15. DAILY DOSE(S) (Continuation...)

Dosage Text :

Drug 1 :Eligard®

1) 45 milligram, q 6 month

2) 45 milligram, q 6 month

22.CONCOMITANT DRUG(S) (Continuation...)

1). Drug : DIGLET
Active Substance : 1) COLECALCIFEROL
Form Strength :
Indications : 1) Product used for unknown indication [10070592 - Product used for unknown indication]
Dosage Text : 1) 10,000 u

2). Drug : OMEGA 3 [FISH OIL]
Active Substance : 1) FISH OIL
Form Strength :
Indications : 1) Product used for unknown indication [10070592 - Product used for unknown indication]

3). Drug : CEFTRIAXONE
Active Substance : 1) CEFTRIAXONE
Form Strength :
Daily Dose : 1) (1 gram(s))
Indications : 1) Drug use for unknown indication [10057097 - Drug use for unknown indication]
Dosage Text : 1) 1 gram

Continuation Sheet for CIOMS report

4). Drug	:	CEFALEXIN
Active Substance	:	1) CEFALEXIN
Form Strength	:	
Daily Dose	:	1) 1000 milligram(s) (500 milligram(s), 1 in 12 Hour)
Indications	:	1) Drug use for unknown indication [10057097 - Drug use for unknown indication]
Dosage Text	:	1) 500mg every 12 hours for 7 days

23. OTHER RELEVANT HISTORY (Continuation...)

2) FOOD ALLERGY (10016946 , Food allergy) (Continuing : YES)