SUSPECT ADVERSE REACTION REPORT

NI-TOLMAR, INC.-25NI056860

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	4-6 REACTION ONSET		
		Day	Month	Year	Years		Day	Month	Year
KAPJ	NICARAGUA	01	Sep	2018	6	Female		Nov	2024

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

1) DEPRESSED/FELT SAD AND DID NOT WANT TO LEAVE THE ROOM, DID NOT WANT TO TAKE A BATH (Depressed mood (10012374), Depressed mood (10012374))
(/Nov/2024 -) - Recovering/Resolving
2) SENSITIVITY TO THE ENVIRONMENT (Sensory processing sensitivity (10087492), Sensory processing sensitivity (10087492))
(/Nov/2024 -) - Recovering/Resolving
3) FEELING WARMTH/FEELING TOO HOT (Feeling of warmth (10016357), Feeling hot (10016334))
(/Nov/2024 -) - Recovering/Resolving
4) Feeling of suffocation (Chest discomfort (10008469), Chest discomfort (10008469))
(24/Feb/2025 -) - Recovered/Resolved

Cont..

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)(Unknown)

Cont..

20. DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☑ NA

15. DAILY DOSE(S)

1) (22.5 milligram(s), 1 in 3 Month)

16. ROUTE(S) OF ADMINISTRATION

1) Subcutaneous

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
(08-Nov-2024 - Ongoing)	

III. CONCOMITANT DRUG(S) AND HISTORY

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

1)LAMOTRIGINA(LAMOTRIGINE)

Cont..

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

1) LENNOX-GASTAUT SYNDROME (10048816, Lennox-Gastaut syndrome) (/Jun/2020 -) (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	NI-TOLMAR, INC.-25NI056860
24c. DATE RECEIVED BY MANUFACTURER	24d. REPORT SOURCE
07/Aug/2025	☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT	25a. REPORT TYPE
16/Aug/2025	☐ INITIAL ☑ FOLLOWUP

= Continuation attached sheet(s)..

Continuation Sheet for CIOMS report

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

5) PATIENT WAS USING 22.5 MG FOR CENTRAL PRECOCIOUS PUBERTY (Off label dosing (10074165), Off label use (10053762)(08/Nov/2024 -) - Unknown)

6) IRRITABLE AND HATEFUL (Irritability (10022998), Irritability (10022998)(/Nov/2024 -) - Recovering/Resolving)

7) DID NOT WANT TO EAT (Appetite lost (10003028), Decreased appetite (10061428)(/Nov/2024 -) - Recovering/Resolving)

8) CRIES FOR EVERYTHING AND FOR NO REASON (Crying (10011469), Crying (10011469)(/Nov/2024 -) - Recovered/Resolved)

9) Sudden urge to cry (Crying (10011469), Crying (10011469)(24/Feb/2025 -) - Recovered/Resolved)

10) Weight gain of approximately 10 pounds (Weight gain (10047896), Weight increased (10047899)(/May/2025 -) - Not Recovered/Not Resolved/Ongoing)

11) Hot flashes (Hot flashes (10020407), Hot flush (10060800)(24/Feb/2025 -) - Recovered/Resolved)

12) SWEATING (Sweating (10042661), Hyperhidrosis (10020642)(/Nov/2024 -) - Recovering/Resolving)

Event Description :

This Study report from NICARAGUA was received by Adium via Patient Support Program (reference number: NI-ADIUM-NI-0014-20250212) on 12-FEB-2025 from a Consumer/Other Non-Health Professional regarding a Child 6 Years old Female patient who experienced Sensitivity to the environment (Sensory processing sensitivity), Feeling warmth (Feeling hot), cries for everything and for no reason (Crying), Did not want to eat (Appetite lost), Irritable and hateful (Irritability), Depressed/felt sad and did not want to leave the room, did not want to take a bath (Feeling of warmth), Sweating (Sweating), during Eligard (Leuprolide acetate) 22.5 milligram 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 17-FEB-2025.

The patient's medical history and current conditions included: Precocious puberty, Autism spectrum disorder, Lennox-Gastaut syndrome.

Concomitant medications included: LAMOTRIGINA, LEVETIRACETAM and RIVOTRIL.

On 08-NOV-2024, the patient began receiving Eligard 22.5 milligram, q 3 month, via Subcutaneous use for Central precocious puberty (Lot numbers and Expiration dates were not reported).

On an unknown date in NOV-2024, two or three weeks after the most recent dose of Eligard, the patient experienced becoming sensitive to the environment, sometimes irritable and hateful. Additionally, the patient experienced being depressed as she did not want to eat, did not want to leave the room, did not want to take a bath, cried about everything for no reason, she felt sad. Also, in NOV-2024, on occasions; the patient felt warmth, which was associated with sweating.

Corrective treatment was not reported.

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

The outcome of Sensory processing sensitivity, feeling of warmth, crying, appetite lost, irritability, depressed mood and sweating was recovering.

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

On 07-May-2025, follow-up information was received by Adium via Patient Support Program (reference number: NI-ADIUM-NI-0014-20250212) from a consumer (non-healthcare professional). New information included: Added four non-serious events of "Hot flashes" (Hot flush), "Patient was using 22.5 mg for Central Precocious Puberty" (Off label use), "Choking" (Choking) and "Sudden urge to cry" (Crying). Added two concomitant medications: Topiramate and Valproic acid. Updated verbatim of events from "Feeling warmth" to "Feeling warmth/Feeling too hot" and from "Cries for everything and for no reason" to "Cries for everything and for no reason, Sudden urge to cry". No further information was available. The report was sent to Tolmar on 09-May-2025.

Concomitant medications were Topiramate and Valproic Acid for the indication Lennox Gastaut Syndrome with which patient experienced nausea and vomiting and thrombocytopenia respectively.

On 08-NOV-2024, the patient began receiving Eligard 22.5 milligram, q 3 month, via Subcutaneous use for Central precocious puberty (Off label use) (Lot numbers and Expiration dates were not reported).

On an unknown date, the patient experienced choking and felt too hot and wanted to take off clothes.

On 24-Feb-2025, the patient experienced hot flashes and sudden urge to cry.

Corrective treatment was not provided.

Continuation Sheet for CIOMS report

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

The outcome of hot flush was recovered.

The outcome of choking was unknown.

The outcome of feeling hot and crying was not recovered.

The reporter did not assess seriousness of hot flush, choking, feeling hot and crying.

The reporter did not provide causality of choking, feeling hot and crying in relationship to Eligard and Eligard unspecified device.

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

No further queries were raised.

On 05-Jun-2025, the follow up was received by Adium via Patient Support Program (reference number: NI-ADIUM-NI-0014-20250212) and sent to Tolmar on 05-Jun-2025. New information included: A new non-serious event of "Feeling of suffocation" (Chest discomfort) was added.

On 24-Feb-2025, the patient experienced the feeling of suffocation due to hot flashes. No further details were reported.

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 chest discomfort was recovered.

The reporter did not assess seriousness of chest discomfort.

The reporter did not provide causality of chest discomfort in relationship to Eligard and Eligard unspecified device.

On 07-Aug-2025, the follow up was received by Adium via Patient Support Program (reference number: NI-ADIUM-NI-0014-20250212) and sent to Tolmar on 08-Aug-2025. New information included: A new non-serious event of "Weight gain of approximately 10 pounds" (Weight increased) was added and lab data of weight gain was added.

On an unknown date in May-2025, the patient experienced Weight gain of approximately 10 pounds. No further details were reported.

Corrective treatment was not required.

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

The outcome of Weight increased was not recovered.

The reporter did not assess seriousness of Weight increased.

The reporter assessed causality of Weight increased in relationship to Eligard as related.

The reporter did not provide causality of Weight increased in relationship to Eligard unspecified device.

No follow up queries were raised.

Listedness:
Labelling of previously reported events retained as per previous assessment.
Off label use>Eligard>Unlisted as per CCDS>07-Nov-2024
Off label use>Eligard>Unlisted as per USPI>Feb-2025
Off label use>Eligard unspecified device>Unlisted as per USPI>Feb-2025
Off label use>Eligard>Unlisted as per Canadian monograph>02-Apr-2025

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

Hot flush>Eligard>listed as per CCDS>07-Nov-2024
Hot flush>Eligard>Unlisted as per USPI>Feb-2025
Hot flush>Eligard unspecified device>Unlisted as per USPI>Feb-2025

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Hot flush>Eligard>listed as per Canadian monograph>02-Apr-2025

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

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

Company Remarks (Sender's Comments) :

Causality of previously reported events retained as per previous assessment:
Evaluator comment (Tolmar): This is regarding a Child 6 Years old Female patient who experienced Sensory processing sensitivity (Sensitivity to the environment), Feeling hot (FEELING WARMTH/FEELING TOO HOT), Crying (cries for everything and for no reason) , decreased appetite (Did not want to eat), Irritability (Irritable and hateful) , Depressed mood (felt sad and did not want to leave the room), Sweating (Sweating), Off label use (the patient began receiving Eligard 22.5 milligram, q 3 month, via Subcutaneous use for Central precocious puberty), hot flush(Hot flashes), crying(Sudden urge to cry) and chest discomfort (feeling of suffocation) during Eligard (Leuprolide acetate) 22.5 milligram therapy for Central precocious puberty. Tolmar assessed the reported events as non-serious since there was no information suggesting any intervention or medical treatment for the reported events. Tolmar assessed crying, decreased appetite, irritability, crying, hyperhidrosis, depressed mood, hot flush as related to Eligard drug based on product safety profile. Sensory processing sensitivity, feeling hot and chest discomfort were assessed as not related to Eligard drug based on inconsistent safety profile. The causality of the event Off label use was assessed as not related to suspect Eligard (drug and device) as the event occurred with the product due to human action, rather than due to the drug. All the reported events were assessed as not related to device component of the drug based on the case information.

FU-Event weight increased (Weight gain of approximately 10 pounds) was added. 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 weight increased was assessed as related to Eligard (drug) considering the consistency with known safety profile and role of drug cannot be excluded from the limited information available and not related to device. Causality of all the events is retained as per previous assessment.

Additional Information (Continuation...)

Lab Result :

Test Name	Test Date	Test Result	Normal Value
WEIGHT GAIN	Unknown		

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

1) Test Name: WEIGHT GAIN

Result Unstructured Data (free text) : Weight gain of approximately 10 pounds
Test Date: Unknown

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 : (22.5 milligram(s), 1 in 3 Month)
Route of Admin : 1) Subcutaneous
Indications : 1) Central Precocious Puberty [10073186 - Central precocious puberty]
Action(s) Taken With Drug : Dose not changed

Causality

1) DEPRESSED/FELT SAD AND DID NOT WANT TO LEAVE THE ROOM, DID NOT WANT TO TAKE A BATH (Depressed mood - 10012374, Depressed mood - 10012374)
Causality as per reporter : Not Reported
Causality as per Mfr : Related
DeChallenge : Not applicable

Continuation Sheet for CIOMS report

ReChallenge : Not Applicable

2) SENSITIVITY TO THE ENVIRONMENT (Sensory processing sensitivity - 10087492, Sensory processing sensitivity - 10087492)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

3) FEELING WARMTH/FEELING TOO HOT (Feeling of warmth - 10016357, Feeling hot - 10016334)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

4) Feeling of suffocation (Chest discomfort - 10008469, Chest discomfort - 10008469)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

5) PATIENT WAS USING 22.5 MG FOR CENTRAL PRECOCIOUS PUBERTY (Off label dosing - 10074165, Off label use - 10053762)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

6) IRRITABLE AND HATEFUL (Irritability - 10022998, Irritability - 10022998)
Causality as per reporter : Not Reported
Causality as per Mfr : Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

7) DID NOT WANT TO EAT (Appetite lost - 10003028, Decreased appetite - 10061428)
Causality as per reporter : Not Reported
Causality as per Mfr : Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

8) CRIES FOR EVERYTHING AND FOR NO REASON (Crying - 10011469, Crying - 10011469)
Causality as per reporter : Not Reported
Causality as per Mfr : Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

9) Sudden urge to cry (Crying - 10011469, Crying - 10011469)
Causality as per reporter : Not Reported
Causality as per Mfr : Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

10) Weight gain of approximately 10 pounds (Weight gain - 10047896, Weight increased - 10047899)
Causality as per reporter : Related
Causality as per Mfr : Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

11) Hot flashes (Hot flashes - 10020407, Hot flush - 10060800)
Causality as per reporter : Related
Causality as per Mfr : Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

12) SWEATING (Sweating - 10042661, Hyperhidrosis - 10020642)
Causality as per reporter : Not Reported
Causality as per Mfr : Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) DEPRESSED/FELT SAD AND DID NOT WANT TO LEAVE THE ROOM, DID NOT WANT TO TAKE A BATH
CORE UnLabeled

2) SENSITIVITY TO THE ENVIRONMENT
CORE UnLabeled

3) FEELING WARMTH/FEELING TOO HOT
CORE UnLabeled

4) Feeling of suffocation
CORE UnLabeled

Continuation Sheet for CIOMS report

5) PATIENT WAS USING 22.5 MG FOR CENTRAL PRECOCIOUS PUBERTY
CORE UnLabeled
6) IRRITABLE AND HATEFUL
CORE Labeled
7) DID NOT WANT TO EAT
CORE Labeled
8) CRIES FOR EVERYTHING AND FOR NO REASON
CORE Labeled
9) Sudden urge to cry
CORE Labeled
10) Weight gain of approximately 10 pounds
CORE Labeled
11) Hot flashes
CORE Labeled
12) SWEATING
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
Route of Admin : 1) Subcutaneous
Indications : 1) Central Precocious Puberty [10073186 - Central precocious puberty]
Action(s) Taken With Drug : Not applicable

Causality

1) DEPRESSED/FELT SAD AND DID NOT WANT TO LEAVE THE ROOM, DID NOT WANT TO TAKE A BATH (Depressed mood - 10012374, Depressed mood - 10012374)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
2) SENSITIVITY TO THE ENVIRONMENT (Sensory processing sensitivity - 10087492, Sensory processing sensitivity - 10087492)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
3) FEELING WARMTH/FEELING TOO HOT (Feeling of warmth - 10016357, Feeling hot - 10016334)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
4) Feeling of suffocation (Chest discomfort - 10008469, Chest discomfort - 10008469)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
5) PATIENT WAS USING 22.5 MG FOR CENTRAL PRECOCIOUS PUBERTY (Off label dosing - 10074165, Off label use - 10053762)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
6) IRRITABLE AND HATEFUL (Irritability - 10022998, Irritability - 10022998)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
7) DID NOT WANT TO EAT (Appetite lost - 10003028, Decreased appetite - 10061428)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
8) CRIES FOR EVERYTHING AND FOR NO REASON (Crying - 10011469, Crying - 10011469)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
9) Sudden urge to cry (Crying - 10011469, Crying - 10011469)

Continuation Sheet for CIOMS report

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

10) Weight gain of approximately 10 pounds (Weight gain - 10047896, Weight increased - 10047899)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related

11) Hot flashes (Hot flashes - 10020407, Hot flush - 10060800)
Causality as per reporter : Related
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

12) SWEATING (Sweating - 10042661, Hyperhidrosis - 10020642)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) DEPRESSED/FELT SAD AND DID NOT WANT TO LEAVE THE ROOM, DID NOT WANT TO TAKE A BATH
CORE
2) SENSITIVITY TO THE ENVIRONMENT
CORE
3) FEELING WARMTH/FEELING TOO HOT
CORE
4) Feeling of suffocation
CORE
5) PATIENT WAS USING 22.5 MG FOR CENTRAL PRECOCIOUS PUBERTY
CORE
6) IRRITABLE AND HATEFUL
CORE
7) DID NOT WANT TO EAT
CORE
8) CRIES FOR EVERYTHING AND FOR NO REASON
CORE
9) Sudden urge to cry
CORE
10) Weight gain of approximately 10 pounds
CORE
11) Hot flashes
CORE
12) SWEATING
CORE

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

Dosage Text :

Drug 1 :Eligard®

1) 22.5 milligram, q 3 month

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

1). Drug : LAMOTRIGINA
Active Substance : 1) LAMOTRIGINE
Form Strength :
Indications : 1) Product used for unknown indication [10070592 - Product used for unknown indication]
Dosage Text : 1) 75 mg every 12 hours

2). Drug : LEVETIRACETAM
Active Substance : 1) LEVETIRACETAM
Form Strength :
Indications : 1) Product used for unknown indication [10070592 - Product used for unknown indication]
Dosage Text : 1) 5 mg every 12 hours.

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3). Drug	:	RIVOTRIL
Active Substance	:	1) CLONAZEPAM
Form Strength	:	
Indications	:	1) Product used for unknown indication [10070592 - Product used for unknown indication]
Dosage Text	:	1) 2.5 mg/ml 12 drops at night

4). Drug	:	TOPIRAMATE
Active Substance	:	1) TOPIRAMATE
Form Strength	:	
Indications	:	1) Lennox Gastaut Syndrome [10048816 - Lennox-Gastaut syndrome]
Therapy Dates	:	1) From : /Jun/2020 To :

5). Drug	:	VALPROIC ACID
Active Substance	:	1) VALPROIC ACID
Form Strength	:	
Indications	:	1) Lennox Gastaut Syndrome [10048816 - Lennox-Gastaut syndrome]
Therapy Dates	:	1) From : /Jun/2020 To :

23. OTHER RELEVANT HISTORY (Continuation...)

2) AUTISM GRADE 2 (10063844 , Autism spectrum disorder) (/Oct/2020 -) (Continuing : YES)

3) NAUSEA (10028813 , Nausea) (/Oct/2020 -) (Continuing : YES)

4) VOMITING (10047700 , Vomiting) (/Oct/2020 -) (Continuing : YES)

5) CENTRAL PRECOCIOUS PUBERTY (10073186 , Central precocious puberty) (Continuing : YES)