SUSPECT ADVERSE REACTION REPORT

HN-Tolmar-TLM-2025-01714

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
RBC	HONDURAS	28	Feb	1950	75	Male	03	May	2025

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

1) had symptoms of food poisoning (Food poisoning (10016952), Food poisoning (10016952))
(03/May/2025 - 04/May/2025) - Recovered/Resolved
2) abdominal distention (Abdominal distension (10000060), Abdominal distension (10000060))
(03/May/2025 - 04/May/2025) - Recovered/Resolved
3) abdominal pain (Abdominal pain (10000081), Abdominal pain (10000081))
(03/May/2025 - 04/May/2025) - Recovered/Resolved
4) nausea (Nausea (10028813), Nausea (10028813))
(03/May/2025 - 04/May/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)(L15276CUY; Unk; Unk)

Cont..

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

15. DAILY DOSE(S)

1) (45 milligram(s), 1 in 24 Week)

Cont..

16. ROUTE(S) OF ADMINISTRATION

1) Subcutaneous

Cont..

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

(NA : Not Applicable)

17. INDICATION(S) FOR USE

1) prostate cancer [10060862 - Prostate cancer]

Cont..

18. THERAPY DATE(S) (from/to)	19. THERAPY DURATION
1) (20/May/2021 - ongoing)	

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) PROSTATE CANCER (10060862, Prostate cancer) (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
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	HN-Tolmar-TLM-2025-01714
24c. DATE RECEIVED BY MANUFACTURER	24d. REPORT SOURCE
12/May/2025	☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT	25a. REPORT TYPE
22/May/2025	☑ INITIAL ☐ FOLLOWUP

= Continuation attached sheet(s)..

Continuation Sheet for CIOMS report

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

5) dizziness (Dizziness (10013573), Dizziness (10013573)(03/May/2025 - 04/May/2025) - Recovered/Resolved)

Event Description :

This study report from Honduras was received by Adium via “Asofarma A Tu Lado” Patient Support Program (reference number: HN-ADIUM-HN-0201-20250512) on 12-May-2025 from a consumer (non-health care professional) regarding a 75-year-old male patient who experienced non-serious events of "had symptoms food poisoning" (food poisoning), "nausea" (nausea), "dizziness" (dizziness), "abdominal pain" (abdominal pain), "abdominal distention" (abdominal distension) during Eligard (leuprolide acetate) 45 mg therapy for prostate cancer. The report was sent to Tolmar on 13-May-2025.

The patient's medical history was unknown and current conditions included prostate cancer and castration-resistant prostate cancer.

Co-suspect medication included Xtandi 40 mg capsules at a dose of 160 mg per day for castration-resistant prostate cancer.

Concomitant medications were not provided.

On 20-May-2021, the patient began receiving Eligard 45 mg, every 24 weeks via subcutaneous route for prostate cancer (Lot number: L15276CUY and Expiration date Aug-2026).

On an unknown date, the patient began receiving Xtandi 160 mg, per day via oral route for castration-resistant prostate cancer (Lot numbers and Expiration dates were not provided).

On 03-May-2025, the patient had symptoms of food poisoning, nausea, dizziness, abdominal pain, abdominal distention. He refers that he thinks it was something he ingested during lunch (lettuce and chicken) and went to the family doctor, but he did not indicate treatment, only increase fluid intake.

Corrective treatment was not reported.

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

On 04-May-2025, the outcome of food poisoning, nausea, dizziness, abdominal pain and abdominal distension was resolved.

The reporter did not assess the seriousness of food poisoning, nausea, dizziness, abdominal pain and abdominal distension.

The reporter did not provide the causality of food poisoning, nausea, dizziness, abdominal pain and abdominal distension in relationship to Eligard and Eligard unspecified device.

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

Listedness
Food poisoning >Eligard® >unlisted as per CCDS Eligard®> 7-Nov-2024
Food poisoning> Eligard® >unlisted as per Canadian Monograph Eligard®> 2-Apr-2025
Food poisoning> Eligard®>unlisted as per USPI Eligard®>Feb-2025
Food poisoning> Eligard® Unspecified Device>unlisted as per USPI Eligard®>Feb-2025

Abdominal pain >Eligard® >unlisted as per CCDS Eligard®> 7-Nov-2024
Abdominal pain> Eligard® >unlisted as per Canadian Monograph Eligard®> 2-Apr-2025
Abdominal pain> Eligard®>unlisted as per USPI Eligard®>Feb-2025
Abdominal pain> Eligard® Unspecified Device>unlisted as per USPI Eligard®>Feb-2025

Abdominal distension >Eligard® >unlisted as per CCDS Eligard®> 7-Nov-2024
Abdominal distension> Eligard® >unlisted as per Canadian Monograph Eligard®> 2-Apr-2025
Abdominal distension> Eligard®>unlisted as per USPI Eligard®>Feb-2025
Abdominal distension> Eligard® Unspecified Device>unlisted as per USPI Eligard®>Feb-2025

Nausea >Eligard® >listed as per CCDS Eligard®> 7-Nov-2024
Nausea> Eligard® >listed as per Canadian Monograph Eligard®> 2-Apr-2025
Nausea> Eligard®>listed as per USPI Eligard®>Feb-2025
Nausea> Eligard® Unspecified Device>listed as per USPI Eligard®>Feb-2025

Dizziness >Eligard® >listed as per CCDS Eligard®> 7-Nov-2024
Dizziness > Eligard® >listed as per Canadian Monograph Eligard®> 2-Apr-2025
Dizziness > Eligard®>listed as per USPI Eligard®>Feb-2025
Dizziness > Eligard® Unspecified Device>listed as per USPI Eligard®>Feb-2025

Company Remarks (Sender's Comments) :

Continuation Sheet for CIOMS report

Evaluator comment (Tolmar): This case is regarding a 75-year-old male patient who experienced had symptoms food poisoning (food poisoning), nausea (nausea), dizziness (dizziness), abdominal pain (abdominal pain), abdominal distention (abdominal distension) during Eligard (leuprolide acetate) 45 mg therapy for prostate cancer. Tolmar assessed the reported events as non-serious since they did not meet the ICH seriousness criteria. The causality of events food poisoning was assessed as not related to suspect Eligard(drug and device) considering inconsistency with safety profile of the drug, the nature of the event and as it could be due something he ingested during lunch (lettuce and chicken). The causality of events nausea, dizziness, abdominal pain and abdominal distension was assessed as not related to suspect Eligard(drug and device) as these could be due food poisoning and not due to drug.

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) L15276CUY; Unk; Unk
Daily Dose	:	(45 milligram(s), 1 in 24 Week)
Route of Admin	:	1) Subcutaneous
Indications	:	1) prostate cancer [10060862 - Prostate cancer]
Therapy Dates	:	1) From : 20/May/2021 To :Continuing
Action(s) Taken With Drug	:	Dose not changed

Causality

1) had symptoms of food poisoning (Food poisoning - 10016952, Food poisoning - 10016952)

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

2) abdominal distention (Abdominal distension - 10000060, Abdominal distension - 10000060)

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

3) abdominal pain (Abdominal pain - 10000081, Abdominal pain - 10000081)

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

4) nausea (Nausea - 10028813, Nausea - 10028813)

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

5) dizziness (Dizziness - 10013573, Dizziness - 10013573)

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

Labeling :

1) had symptoms of food poisoning	
CORE	UnLabeled
2) abdominal distention	
CORE	UnLabeled
3) abdominal pain	
CORE	UnLabeled
4) nausea	
CORE	Labeled
5) dizziness	
CORE	Labeled

2) Drug	:	Eligard® Unspecified Device (Leuprolide acetate)
Active Substance	:	1) Leuprolide acetate
Drug Characterization	:	Suspect
Form of Admin	:	1) Injection

Continuation Sheet for CIOMS report

Lot Number : 1) L15276CUY; Unk; Unk
Route of Admin : 1) Subcutaneous
Indications : 1) Prostate cancer [10060862 - Prostate cancer]
Action(s) Taken With Drug : Not applicable

Causality

1) had symptoms of food poisoning (Food poisoning - 10016952, Food poisoning - 10016952)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
2) abdominal distention (Abdominal distension - 10000060, Abdominal distension - 10000060)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
3) abdominal pain (Abdominal pain - 10000081, Abdominal pain - 10000081)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
4) nausea (Nausea - 10028813, Nausea - 10028813)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
5) dizziness (Dizziness - 10013573, Dizziness - 10013573)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) had symptoms of food poisoning
CORE
2) abdominal distention
CORE
3) abdominal pain
CORE
4) nausea
CORE
5) dizziness
CORE

3) Drug : XTANDI
Active Substance : 1) ENZALUTAMIDE
Drug Characterization : Suspect
Form of Admin : 1) Capsule
Lot Number : 1) Unknown
Daily Dose : (160 milligram(s), 1 in 1 Day)
Route of Admin : 1) Oral
Indications : 1) castration-resistant prostate cancer [10076506 - Castration-resistant prostate cancer]
Action(s) Taken With Drug : Dose not changed

Causality

1) had symptoms of food poisoning (Food poisoning - 10016952, Food poisoning - 10016952)
Causality as per reporter : Not Reported
DeChallenge : Not applicable
ReChallenge : Not Applicable
2) abdominal distention (Abdominal distension - 10000060, Abdominal distension - 10000060)
Causality as per reporter : Not Reported
DeChallenge : Not applicable
ReChallenge : Not Applicable
3) abdominal pain (Abdominal pain - 10000081, Abdominal pain - 10000081)
Causality as per reporter : Not Reported
DeChallenge : Not applicable
ReChallenge : Not Applicable

Continuation Sheet for CIOMS report

4) nausea (Nausea - 10028813, Nausea - 10028813)
Causality as per reporter : Not Reported
DeChallenge : Not applicable
ReChallenge : Not Applicable
5) dizziness (Dizziness - 10013573, Dizziness - 10013573)
Causality as per reporter : Not Reported
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) had symptoms of food poisoning
CORE
2) abdominal distention
CORE
3) abdominal pain
CORE
4) nausea
CORE
5) dizziness
CORE

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

Dosage Text :

Drug 1 :Eligard®

1) 1 LIO x 1 JER

Drug 3 :XTANDI

1) 40 MG x 120 CAP x 30 FND

23. OTHER RELEVANT HISTORY (Continuation...)

2) CASTRATION-RESISTANT PROSTATE CANCER (10076506 , Castration-resistant prostate cancer) (Continuing : YES)