SUSPECT ADVERSE REACTION REPORT

DO-TOLMAR, INC.-22DO036660

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	
HP	DOMINICAN Cont..	10	Nov	1938	83	Male	03	Apr	2025	

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

1) Deafness (Deafness (10011878), Deafness (10011878))
Unknown
2) is half crooked (Ill-defined disorder (10061520), Ill-defined disorder (10061520))
(03/Apr/2025 -) - Unknown
3) HARD OF HEARING (Hypoacusis (10048865), Hypoacusis (10048865))
Unknown

- ☐ 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) (22.5 Milligram, 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) Prostate cancer [10060862 - Prostate cancer]

18. THERAPY DATE(S) (from/to)	19. THERAPY DURATION
1) (06/Apr/2022 - 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)

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	DO-TOLMAR, INC.-22DO036660
24c. DATE RECEIVED BY MANUFACTURER	24d. REPORT SOURCE
03/Apr/2025	☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT	25a. REPORT TYPE
14/Apr/2025	☑ INITIAL ☐ FOLLOWUP

= Continuation attached sheet(s)..

Continuation Sheet for CIOMS report

1a. COUNTRY

DOMINICAN REPUBLIC

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

Event Description :

This study report from Dominican Republic was received by Adium ((reference number: (DO-0120-20220915) on 14-Sep-2022, from a consumer regarding an elderly-83 year old male patient who experienced a non-serious event of ‘hard of hearing' (Hypoacusis) during Eligard (leuprolide acetate) 22.5 mg therapy for prostate cancer. The needle component of the constituent device was not identified in the report. The report was sent to Tolmar on 15-Sep-2025.

The patient's medical history was unknown and current condition included prostate cancer.

Concomitant medications were unknown.

On an unknown date, the patient began receiving Eligard 22.5 mg every 3 months via subcutaneous route for prostate cancer (Lot numbers and expiration dates were not reported). No further details were provided.

On an unknown date, the patient did not hear well due to his age. No further details were provided.

Corrective treatment was unknown.

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

The outcome of hypoacusis was Unknown.

The reporter did not assess the seriousness of event hypoacusis.

The reporter did not provide the causality of hypoacusis in relationship to Eligard and Eligard Unspecified Device.

On 03-Apr-2025, follow up information was received by Adium (Reference number: DO-0120-20220915) via e-mail from Patient Support Programme. New information included: Eligard dose added. New serious event (medically significant) of ‘deafness' (deafness) and non-serious event of ‘is half crooked' (ill-defined disorder) were added.

On 06-Apr-2022, the patient began receiving Eligard 22.5 mg every 3 months via subcutaneous route for prostate cancer (Lot numbers and expiration dates were not reported).

On an unknown date, the patient was half deaf.

On 03-Apr-2025, the patient was half crooked. No further details were provided.

On 04-Apr-2025, the patient would be seeing his doctor.

Corrective treatment was unknown.

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

The outcome of deafness and ill-defined disorder was unknown.

The reporter did not assess the seriousness of deafness and ill-defined disorder.

The reporter did not provide the causality of deafness and ill-defined disorder in relationship to Eligard and Eligard Unspecified Device.

Note: Listedness of the previously reported event "Hypoacusis" is retained as per previous assessment

Company Remarks (Sender's Comments) :

Causality of the previously reported event "Hypoacusis" is retained as per previous assessment.

Follow-up-serious event (medically significant) deafness' (deafness) and non-serious event of ill-defined disorder (‘is half crooked') were added during Eligard (leuprolide acetate) 22.5 mg therapy for prostate cancer. Tolmar assessed ill-defined disorder as non-serious since it did not meet ICH seriousness criteria. Deafness, and ill-defined disorder, were assessed as not related to Eligard (drug and device) as events are probably associated with age-related sensory-neuronal degenerative disorder.

Continuation Sheet for CIOMS report

14.SUSPECT DRUG(S) (Continuation...)

Product-Reaction Level

1) Drug : Eligard (Leuprolide acetate)
Active Substance : 1) Leuprolide acetate
Drug Characterization : Suspect
Form Strength : 1) 22.5 Milligram
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) Prostate cancer [10060862 - Prostate cancer]
Therapy Dates : 1) From : 06/Apr/2022 To :Continuing
Action(s) Taken With Drug : Dose not changed

Causality

1) Deafness (Deafness - 10011878, Deafness - 10011878)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
2) is half crooked (Ill-defined disorder - 10061520, Ill-defined disorder - 10061520)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
3) HARD OF HEARING (Hypoacusis - 10048865, Hypoacusis - 10048865)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) Deafness
CORE UnLabeled
2) is half crooked
CORE UnLabeled
3) HARD OF HEARING
CORE UnLabeled

2) Drug : Eligard Unspecified Device (Leuprolide acetate)
Active Substance : 1) Leuprolide acetate
Drug Characterization : Suspect
Form of Admin : 1) Injection
Lot Number : 1) Unknown
Indications : 1) Prostate cancer [10060862 - Prostate cancer]
Action(s) Taken With Drug : Not applicable

Causality

1) Deafness (Deafness - 10011878, Deafness - 10011878)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
2) is half crooked (Ill-defined disorder - 10061520, Ill-defined disorder - 10061520)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable
3) HARD OF HEARING (Hypoacusis - 10048865, Hypoacusis - 10048865)
Causality as per reporter : Not Reported
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

Continuation Sheet for CIOMS report

1) Deafness
   CORE
2) is half crooked
   CORE
3) HARD OF HEARING
   CORE

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

Dosage Text :

Drug 1 :Eligard®

1) 22.5 mg every 3 months