SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET Day	Month	Year
PRIVACY	COSTA RICA		PRIVACY		78 Years	Male	Unk		Unk	

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

Other Serious Criteria: Medically significant
I had surgery, a curettage of my prostate because it was very enlarged [Prostatomegaly]

Case Description: This spontaneous case, reported by a consumer via a manufacturer, who contacted the company to report adverse event, concerns a 78-year-old male patient of unknown origin.

Medical history included prostate enlargement, high blood pressure, and a normal biopsy. Concomitant medications were not reported.

(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

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) Cymbalta 30mg (Duloxetine Hydrochloride) Capsule, 30 mg
#2) TAMSULON (TAMSULOSIN HYDROCHLORIDE) Capsule, 0.4 mg **(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) 30 mg, unknown	#1) Oral
#2) UNK, unknown	#2) Oral

17. INDICATION(S) FOR USE
#1) drug use for unknown indication (Produc
#2) prostate enlargement (Prostatomegaly) **(Continued on Additional Information Page)**

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 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)

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

From/To Dates	Type of History / Notes	Description
Unknown	Medical Condition	Enlarged prostate (Prostatomegaly)
Unknown	Medical Condition	Blood pressure high (Hypertension)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
Eli Lilly Interamerica Inc (AR Branch)
Tronador 4890 - Piso 12
Buenos Aires, Capital Federal CP: 1430 ARGENTINA
Phone: 54 1145464000

26. REMARKS

24b. MFR CONTROL NO.
CR202505019439

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

NAME AND ADDRESS WITHHELD.

24c. DATE RECEIVED BY MANUFACTURER
20-MAY-2025

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

DATE OF THIS REPORT
25-MAY-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: CR202505019439

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The patient received duloxetine hydrochloride (Cymbalta), 30 mg, unknown frequency, orally, for the treatment of an unknown indication, beginning on an unknown date. He also received tamsulosin hydrochloride (Tamsulon 0.4 mg) and dutasteride, tamsulosin hydrochloride (Tamsulon duo 0.4 mg / 0.5 mg), both for unknown dose and frequency, orally, for prostate enlargement; pramipexole dihydrochloride monohydrate (Parmital 0.25 mg), one dosage form, daily, orally, for high blood pressure. On an unspecified date (reported as a year and half ago), while on duloxetine, tamsulosin, dutasteride, tamsulosin; and pramipexole dihydrochloride monohydrate therapy, the patient had surgery, a curettage of his prostate because it was very enlarged. The event of enlarged prostate was assessed as serious by the company due to medically significant reasons. Information regarding diagnostic testing was not provided. The outcome of event was unknown. The status of duloxetine therapy was not changed, while the status of tamsulosin, dutasteride, tamsulosin; and pramipexole dihydrochloride monohydrate was unknown.

The initial reporting consumer did not provide a relatedness assessment of event enlarged prostate with duloxetine, tamsulosin, dutasteride, tamsulosin; and pramipexole dihydrochloride monohydrate therapy. The manufacturer did not relate the event with duloxetine, tamsulosin, and dutasteride, tamsulosin.

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) Cymbalta 30mg (Duloxetine Hydrochloride) Capsule, 30 mg; Regimen #1	30 mg, unknown; Oral	drug use for unknown indication (Product used for unknown indication)	Ongoing; Unknown
#3) TAMSULON DUO (DUTASTERIDE, TAMSULOSIN HYDROCHLORIDE) Capsule, 0.4 / 0.5 mg; Regimen #1	UNK, unknown; Oral	prostate enlargement (Prostatomegaly)	Unknown; Unknown
#4) PARMITAL (PRAMIPEXOLE DIHYDROCHLORIDE MONOHYDRATE) Tablet, 0.25 mg; Regimen #1	1 dosage form, daily; Oral	high blood pressure (Hypertension)	Unknown; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown	Medical Condition normal	Biopsy (Biopsy);