CIOMS FORM

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	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
PRIVACY	COSTA RICA		PRIVACY		64 Years	Female	Unk		Unk		

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

Did not did her well [Ill-defined disorder]
Made her half dizzy [Dizziness]

Case Description: Patient Demographics: 64 Years old Female

Event(s): Did not did her well, Made her half dizzy

Suspect Product(s) (Name, IFU): cymbalta 30mg (duloxetine hydrochloride) for treatment of For fibromyalgia pain

(Continued on Additional Information Page)

- ☐ 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

15. DAILY DOSE(S)
#1) 1 dosage form, daily

16. ROUTE(S) OF ADMINISTRATION
#1) Oral

17. INDICATION(S) FOR USE
#1) For fibromyalgia pain (Fibromyalgia)

18. THERAPY DATES(from/to)
#1) 2021 / 2023

19. THERAPY DURATION
#1) Unknown

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

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

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) ALTRULINE (SERTRALINE HYDROCHLORIDE) Unknown ; Unknown
#2) IRBESARTAN (IRBESARTAN) Unknown ; Unknown

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 very old	Movement disorder (Movement disorder)

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.
CR202507002763

24c. DATE RECEIVED BY MANUFACTURER
28-JUN-2025

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

DATE OF THIS REPORT
03-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Action(s) Taken: cymbalta 30mg (duloxetine hydrochloride) - Drug Discontinued

Event Outcome(s): Did not did her well (Unknown), Made her half dizzy (Unknown)

Reporter's Opinion of Relatedness: cymbalta 30mg (duloxetine hydrochloride) - Did not did her well (Not Reported) , Made her half dizzy (Not Reported)