SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year				Day	Month	Year	
PRIVACY	COSTA RICA		PRIVACY		Unk	Unk	Unk		Unk		

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

they were for daily use [Off label dosing frequency]

Case Description: This is a spontaneous report received from a Consumer or other non HCP from medical information team.

A patient (age and gender not provided) received cabergoline (DOSTINEX). The patient's relevant medical history was not reported.

(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) Dostinex (CABERGOLINE) Tablet

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) UNK	#1) Unknown

17. INDICATION(S) FOR USE
#1) Unknown

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) Unknown	#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
#2) EUTEBROL (MEMANTINE HYDROCHLORIDE) ; Unknown
#3) DEPAX (SERTRALINE HYDROCHLORIDE) ; Unknown
#4) TRESIBA FLEXTOUCH (INSULIN DEGLUDEC) ; Unknown
#5) COVERAM (AMLODIPINE BESILATE, PERINDOPRIL ARGININE) ; Unknown
#6) XIGDUO XR (DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE, ME

(Continued on Additional Information Page)

23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)
From/To Dates Type of History / Notes Description
Unknown

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
Pfizer S.A.
Laura Arce Mora
Avenida Escazú, Torre Lexus, piso 7. Escazú
San Jose, COSTA RICA

26. REMARKS

24b. MFR CONTROL NO.
202500143705

24c. DATE RECEIVED BY MANUFACTURER
11-JUL-2025

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

DATE OF THIS REPORT
16-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Concomitant medication(s) included: ALTRULINE; EUTEBROL; DEPAX; TRESIBA FLEXTOUCH; COVERAM; XIGDUO XR.
The following information was reported: OFF LABEL USE (non-serious), described as "they were for daily use". The action taken for cabergoline was unknown.

Additional Information: Patient wanted to know if she could purchase some medications directly from them, as they were for daily use

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION continued

#6) XIGDUO XR (DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE, METFORMIN HYDROCHLORIDE) ; Unknown