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	Female	Unk		Unk		

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

Feel very bad [Feeling unwell]
Migraine attacks/Head swollen/ vascular inflammation/ pain in the temples and the eyes/In some areas of the head, she felt like a pressure [Migraine]
pain in the nape of the neck on the 2 sides [Neck pain]
Sleepy/still felt groggy [Sleepy]
High blood pressure/139/97mmHg, 130/90 mmHg [Blood pressure high]
Energy decreased [Energy decreased]
Splitting the tablet in half [Unapproved splitting of product]
told me to take the pristiq for a week and take the venlafaxine together with a Pristiq/I did not take those 2 pills together/from Saturday I

(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) Pristiq (DESVENLAFAXINE SUCCINATE MONOHYDRATE) Prolonged-release tablet

(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) 50 mg, 1x/day	#1) Unknown

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

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 29-MAY-2025 / Unknown	#1) 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
MAR-2025 to Unknown	Past Drug Event 75 mg	
MAR-2025 to Unknown	Past Drug Event 75 mg	

(Continued on Additional Information Page)

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.
PV202500070257

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

24c. DATE RECEIVED BY MANUFACTURER
01-AUG-2025

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

DATE OF THIS REPORT
06-AUG-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

started taking half a Pristiq [Intentional misuse by dose change]

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

A female patient received desvenlafaxine succinate monohydrate (PRISTIQ), first regimen since 29May2025 at 50 mg 1x/day and second regimen at 0.5 DF 1x/day. The patient's relevant medical history included: "Menopausia" (unspecified if ongoing); "Migraine attacks" (unspecified if ongoing); "Generalized Anxiety Disorder" (unspecified if ongoing); "Depression" (unspecified if ongoing); "Suicidal ideation" (unspecified if ongoing). The patient's concomitant medications were not reported. Past drug history included: Venlafaxine hcl, start date: Mar2025, reaction(s): "dizziness", notes: 75 mg; Venlafaxine hcl, start date: Mar2025, reaction(s): "somnolence", notes: 75 mg; Venlafaxine hcl, start date: Mar2025, reaction(s): "Xerostomia", notes: 75 mg; Venlafaxine hcl, start date: Mar2025, reaction(s): "constipation", notes: 75 mg; Venlafaxine hcl, start date: Mar2025, reaction(s): "swollen colon", notes: 75 mg; Venlafaxine hcl, start date: Mar2025, reaction(s): "Emotional low", notes: 75 mg.
The following information was reported: MALAISE (non-serious), outcome "not recovered", described as "Feel very bad"; MIGRAINE (non-serious), outcome "unknown", described as "Migraine attacks/Head swollen/ vascular inflammation/ pain in the temples and the eyes/In some areas of the head, she felt like a pressure"; NECK PAIN (non-serious), outcome "unknown", described as "pain in the nape of the neck on the 2 sides"; SOMNOLENCE (non-serious), 10 min after the suspect product(s) administration, outcome "not recovered", described as "Sleepy/still felt groggy"; HYPERTENSION (non-serious), outcome "unknown", described as "High blood pressure/139/97mmHg, 130/90 mmHg"; ASTHENIA (non-serious), outcome "unknown", described as "Energy decreased"; WRONG TECHNIQUE IN PRODUCT USAGE PROCESS (non-serious), outcome "unknown", described as "Splitting the tablet in half"; INTENTIONAL PRODUCT MISUSE (non-serious), outcome "unknown", described as "told me to take the pristiq for a week and take the venlafaxine together with a Pristiq/I did not take those 2 pills together/from Saturday I started taking half a Pristiq". Relevant laboratory tests and procedures are available in the appropriate section. The action taken for desvenlafaxine succinate monohydrate was dosage reduced. Therapeutic measures were taken as a result of migraine, neck pain.

Additional Information: The patient reported that she started taking Venlafaxine on Mar2025, she was in her third box. Patient reported some dizziness, somnolence, strong mouth dryness (xerostomia), constipation and colon really swollen with Venlafaxine. The somnolence went away later and she started to feel better, she did not get headaches, high blood pressure, and she started to feel good, but 3 months later she had an emotional low, patient stated she was suffering of menopausal conditions, so it all got mixed together. Patient then went to a psychiatrist 15 days ago (on a Wednesday) and told her what she had experienced. Patient told the psychiatrist that she had been on many antidepressants before, but mostly to avoid frequent and chronic migraine attacks, that the medication she was on (Venlafaxine) had helped at least in the emotional part but the side effects were strong and she felt she needed a bit more. Doctor explained that with a higher dose, the side effects increased, so the psychiatrist gave her the option of trying Desvenlafaxine (PRISTIQ). The patient was soon to be 15 days on treatment with PRISTIQ, the physician told her to change the medication from one day to the next, on Wednesday she took venlafaxine and on Thursday she started with desvenlafaxine. Patient stated that the physician did not tell her anything about going little by little or anything like that. Patient reported that since she started taking desvenlafaxine (PRISTIQ) she started to feel very bad; very sleepy, she started having terrible migraine attacks, she lasted like that like 4 days. Patient mentioned having migraines before in other occasions with attacks like this, but she has taken her blood pressure measurements and it had been usually low. Patient was not sure if her blood pressure had increased as she wasn't able to measure it. Patient mentioned started feeling a bit better by Monday after taking a lot of pain killers to reduce the pain, and her headache intensity reduced, but every day she felt her head "like swollen, like her veins or vascular, her temples hurt, the back of the neck and her eyes hurt; her forehead and the top of her head did not hurt". Patient then reported having her blood pressure high, compared to how she normally had, which normally was around 110/70, then normal 120/80, but these days she had her blood pressure measured at 139/97, 130/90. Patient stated she didn't know if this was the cause of her headache. Patient mentioned taking PRISTIQ in the morning, 50mg, then 10-15 min later her few energy went down and she just wanted to sleep all day, she woke up groggy as she didn't sleep, just wanting to sleep. Patient also mentioned the Xerostomia and Colitis went down a lot but were not recovered. According to the patient, the side effects she had from the PRISTIQ were worse than those she had with venlafaxine. Patient stated that since the headaches were so strong, the physician told the patient to take venlafaxine along with (desvenlafaxine) PRISTIQ for a week to reduce the effects, but the patient did not follow the indication because she thought it was very strong and did not want to take the risk. Since Saturday the patient started taking half Pristiq, splitting the tablet in half. Patient stated that she still felt groggy, felt the same way. Additionally, patient stated she forgot to mention that at that moment, the physician diagnosed her with general anxiety disorder and depression. The physician asked her if she had suicidal attempts and stuff, which the patient denied, not to that point, stating that "she has not gotten there or want to get there, but sometimes I do feel really sad that I want that, but no, not to that point". As of 01Aug2025, patient reported ''feeling unwell'.

Follow-up (01Aug2025): This is a spontaneous follow-up report received from reporter(s) Consumer. Updated information: outcome of event ''feeling unwell'' updated to ''not recovered'', clinical course.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Blood pressure measurement	139/97 mmHg	
2		Blood pressure measurement	110/70 mmHg	

Mfr. Control Number: PV202500070257

ADDITIONAL INFORMATION

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
		(Baseline)		
3		Blood pressure measurement	121/86 mmHg	
4		Blood pressure measurement	130/95 mmHg	
5		Blood pressure measurement	120/80 mmHg	
6		Heart rate	88 per min	
7		Heart rate	76 per min	

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) Pristiq (DESVENLAFAXINE SUCCINATE MONOHYDRATE) Prolonged-release tablet; Regimen #2	0.5 DF, 1x/day; Unknown	Unknown	Unknown; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
MAR-2025 to Unknown	Past Drug Event 75 mg	Venlafaxine HCL (VENLAFAXINE HCL); Drug Reaction: Dizziness (Dizziness)
MAR-2025 to Unknown	Past Drug Event 75 mg	Venlafaxine HCL (VENLAFAXINE HCL); Drug Reaction: Somnolence (Somnolence)
MAR-2025 to Unknown	Past Drug Event 75 mg	Venlafaxine HCL (VENLAFAXINE HCL); Drug Reaction: Xerostomia (Dry mouth)
MAR-2025 to Unknown	Past Drug Event 75 mg	Venlafaxine HCL (VENLAFAXINE HCL); Drug Reaction: Constipation (Constipation)
MAR-2025 to Unknown	Past Drug Event 75 mg	Venlafaxine HCL (VENLAFAXINE HCL); Drug Reaction: Colitis (Colitis)
MAR-2025 to Unknown	Past Drug Event 75 mg	Venlafaxine HCL (VENLAFAXINE HCL); Drug Reaction: Emotional reaction (Emotional disorder)
Unknown	Relevant Med History	Menopause (Menopause);
Unknown	Relevant Med History	Migraine (Migraine);
Unknown	Relevant Med History	Generalized anxiety disorder (Generalised anxiety disorder);
Unknown	Relevant Med History	Depression (Depression);
Unknown	Relevant Med History	Suicidal ideation (Suicidal ideation);

ADDITIONAL INFORMATION

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description