SUSPECT ADVERSE REACTION REPORT

2025A-1400819

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE Years	3. SEX	4-6 REACTION ONSET		
		Day	Month	Year			Day	Month	Year
Masked	COSTA RICA	Masked	Masked	Masked	32	Male	01	Jun	2025

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

1) Pruritus with Ciblex use (Pruritus (10037087), Pruritus (10037087))
(01-Jun-2025 - 26-Jun-2025) - Recovering/Resolving
2) Patient consumed 3 daily tablets (Accidental dose increase (10074988), Wrong dose (10080304))
Unknown
3) Patient decide to suspend CIBLEX by own decision (Therapy cessation by patient (10072907), Therapy cessation (10065154))
Unknown

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ 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) CIBLEX_(MIRTAZAPINA_30_MG)_30_TABLETAS_RECUBIERTAS (00Y154) (MTZP>MIRTAZAPINE, MIRTAZAPINE) (Suspect) (Coated tablet)(Unknown)(Unknown)

Continued

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
1) 90.0 milligram(s) (30 milligram(s), 3 in 1 Day)	1) Oral
2) 90.0 milligram(s) (30 milligram(s), 3 in 1 Day)	2) Oral

17. INDICATION(S) FOR USE

1) Generalized anxiety disorder [10018105 - Generalized anxiety disorder]

18. THERAPY DATE(S) (from/to)	19. THERAPY DURATION
1) (02-Dec-2024 - 26-Jun-2025)	1) 207 Days

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

21. DID EVENT REAPPEAR AFTER REINTRODUCTION ☐ YES ☐ NO ☑ NA

(NA : Not Applicable)

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

1)Tafil(ALPRAZOLAM)

Continued

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

UNK

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER

Name : ABBOTT GPV
Thomas Nisslein,
Freundallee 9A, Hannover, 30173, GERMANY
pv.qppv@abbott.comand49-3514-5116750

24.REPORT NULLIFIED	24b. MFR CONTROL NO.
☐ YES ☐ NO	2025A-1400819
24c. DATE RECEIVED BY MANUFACTURER	24d. REPORT SOURCE
29-Jul-2025	☐ STUDY ☐ LITERATURE ☑ HEALTH PROFESSIONAL
DATE OF THIS REPORT	25a. REPORT TYPE
06-Aug-2025	☑ INITIAL ☐ FOLLOWUP

= Continuation attached sheet(s)..

Continuation Sheet for CIOMS report

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

Event Description :

On 10-Jul-2025 a spontaneous valid report was received from a Physician in COSTA RICA concerning a 32 Year(s) old Male patient, who experienced Patient consumed 3 daily tablets, Patient decide to suspend CIBLEX by own decision and Pruritus with Ciblex use, under treatment with CIBLEX_(MIRTAZAPINA_30_MG)_30_TABLETAS_RECUBIERTAS (00Y154).

The patient initiated treatment on CIBLEX_(MIRTAZAPINA_30_MG)_30_TABLETAS_RECUBIERTAS (00Y154) on 02-Dec-2024. CIBLEX_(MIRTAZAPINA_30_MG)_30_TABLETAS_RECUBIERTAS (00Y154) was administered as Coated tablet, Oral, (30 milligram(s), 3 every 1 Day), from 02-Dec-2024 to 26-Jun-2025. Indication for use was Generalized anxiety disorder. The lot number was reported as Unknown, Unknown. Additional Drug Information: Lot Expiration Date: UNKNOWN.

On 01-Jun-2025 the patient experienced Pruritus with Ciblex use. The event was considered non serious.
On an unknown date the patient experienced Patient consumed 3 daily tablets. The event was considered non serious.
On an unknown date the patient experienced Patient decide to suspend CIBLEX by own decision. The event was considered non serious.

The event Pruritus with Ciblex use is recovering.
The outcome of the event Patient consumed 3 daily tablets was unknown.
The outcome of the event Patient decide to suspend CIBLEX by own decision was unknown.

CIBLEX_(MIRTAZAPINA_30_MG)_30_TABLETAS_RECUBIERTAS (00Y154) was discontinued on 26-Jun-2025.

Concomitant medication included Tafil.

There were no concomitant diseases reported.
There was no past medical history reported.

Causality assessment for CIBLEX_(MIRTAZAPINA_30_MG)_30_TABLETAS_RECUBIERTAS (00Y154)
Reporter causality for the event Pruritus with Ciblex use: Possible
Reporter causality for the event Patient consumed 3 daily tablets: Not Reported
Reporter causality for the event Patient decide to suspend CIBLEX by own decision: Not Reported

The following information was reported:

Patient which had been taking CIBLEX and TAFIL for about 7 months, confusing medical indication, increases CIBLEX dose to 3 daily tablets (90 mg) instead of increasing TAFIL dose (which was the actual recommendation given by the doctor). Then patient initiates with pruritus, which makes patient decide to suspend CIBLEX by own decision.
According to local monography:
Pruritus: unexpected.

Follow up information was received on 29-Jul-2025 from physician.
The patient’s demographic added like age, height, weight etc. Indication updated from unknown to Generalized anxiety disorder for suspect drug and therapy details added. Event onset and cessation date added for event Pruritus with Ciblex use and reporter causality updated for this event.

The following questions were answered by the physician:
- If you are the patient, do you agree that Abbott Pharmacovigilance may contact the prescribing physician? If yes, please provide contact information (name, email, and phone number): No
- Actions taken regarding the adverse reaction OR Lack of efficacy (medication to treat the ADR, recommendations for dosing, etc.) Discontinuation of medication (patient's decision without consulting the physician)
- Has the product ever been discontinued and readministered? No
Concomitant medical conditions: None
All the information was received. No more safety information.

Abbott Comment:

Continuation Sheet for CIOMS report

Cessation date was reported for event Pruritus with Ciblex use as 26-Jun-2025 and event outcome conflictingly as recovering.

Pharmacovigilance Comments :

Additional Report Source:
Spontaneous,Spontaneous

Patient Additional Information:
Height: 160 Centimeters
Weight: 90 Kilograms

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

Product-Reaction Level

1) Drug	:	CIBLEX_(MIRTAZAPINA_30_MG)_30_TABLETAS_RECUBIERTAS (00Y154) (MTZP>MIRTAZAPINE)
Active Substance	:	1) MIRTAZAPINE
Drug Characterization	:	Suspect
Form of Admin	:	1) Coated tablet
		2) Coated tablet
Lot Number	:	1) Unknown
		2) Unknown
Daily Dose	:	1) 90.0 milligram(s) (30 milligram(s), 3 in 1 Day)
		2) 90.0 milligram(s) (30 milligram(s), 3 in 1 Day)
Route of Admin	:	1) Oral
		2) Oral
Indications	:	1) Generalized anxiety disorder [10018105 - Generalized anxiety disorder]
Therapy Dates	:	1) From : 02-Dec-2024 To :26-Jun-2025
Therapy Duration	:	1) 207 Days
Action(s) Taken With Drug	:	Drug withdrawn

Causality

1) Pruritus with Ciblex use (Pruritus - 10037087, Pruritus - 10037087)

Causality as per reporter	:	Possible
Causality as per Mfr	:	Possible
DeChallenge	:	Positive
ReChallenge	:	Not Applicable

2) Patient consumed 3 daily tablets (Accidental dose increase - 10074988, Wrong dose - 10080304)

Causality as per reporter	:	Not Reported
Causality as per Mfr	:	Possible
DeChallenge	:	Unknown
ReChallenge	:	Not Applicable

3) Patient decide to suspend CIBLEX by own decision (Therapy cessation by patient - 10072907, Therapy cessation - 10065154)

Causality as per reporter	:	Not Reported
Causality as per Mfr	:	Possible
DeChallenge	:	Unknown
ReChallenge	:	Not Applicable

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

Dosage Text :
Drug 1 :MTZP>MIRTAZAPINE

1) physician did not prescribe that dose; patient decided to take it after confusing Ciblex with Tafil-3 tab daily (90 mg)

22.CONCOMITANT DRUG(S) (Continuation...)

1). Drug	:	Tafil
Active Substance	:	1) ALPRAZOLAM
Form Strength	:	
Dosage Text	:	1) 0.25 to 1.5mg per day PRN (as the thing is needed)