CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

2024A-1389787

## 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 | HONDURAS | UNK | UNK | UNK | 40 | Female | UNK | UNK | 2024 |

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

1) bleeding (Bleeding (10005103), Haemorrhage (10055798))
(??-??-2024 - ) - Recovered/Resolved
2) small bruises (ecchymosis) (Ecchymosis (10014080), Ecchymosis (10014080))
Unknown
3) Off label (see 2 indications) (Off label use in unapproved indication (10084345), Off label use (10053762))
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) Quetidin 25 mg (QUET>QUETIAPINE, QUETIAPINE) (Suspect) (Capsule)(Unknown)

Continued

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

15. DAILY DOSE(S)

UNK

16. ROUTE(S) OF ADMINISTRATION

1) Oral

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

(NA : Not Applicable)

17. INDICATION(S) FOR USE

1) obsessive compulsive disorder [10029898 - Obsessive-compulsive disorder]

| 18. THERAPY DATE(S) (from/to) | 19. THERAPY DURATION |
|---|---|
| 1) (??-??-2020 - ??-Jul-2024) | 1) 54 Months |

## III. CONCOMITANT DRUG(S) AND HISTORY

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

1)Dormilan (Zolpidem)(ZOLPIDEM)

Continued

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

UNK

Continued

## 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

Study Information
Study Name: Abox (PSP)
EudraCT Number: UNK
Protocol No.: 4272
Center No.: UNK
Subject Id : UNK

| 24.REPORT NULLIFIED | 24b. MFR CONTROL NO. |
|---|---|
| ☐ YES ☑ NO | 2024A-1389787 |
| 24c. DATE RECEIVED BY MANUFACTURER | 24d. REPORT SOURCE |
| 10-Apr-2025 | ☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL |
| DATE OF THIS REPORT | 25a. REPORT TYPE |
| 09-May-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 :

Protocol Number: 4272, a Patient Support Program
Study description: Abox (PSP).
This case narrative includes information received on 04-Oct-2024 and 07-Oct-2024.
On 04-Oct-2024 a solicited valid report was received from a Consumer or other non health professional in HONDURAS concerning a 40 Year(s) old Female patient, who experienced small bruises (ecchymosis), Off label (see 2 indications) and bleeding under treatment with Quetidin 25 mg, Capsule, Oral. Indication for use was obsessive compulsive disorder and anxiety.

This case has not been medically confirmed. The patient initiated treatment on Quetidin 25 mg on 2020.

For Quetidin 25 mg the lot number was reported as Unknown.

On 2024 the patient experienced bleeding. The event was considered non serious.
On an unknown date the patient experienced small bruises (ecchymosis). The event was considered non serious.
On an unknown date the patient experienced Off label (see 2 indications). The event was considered non serious.

The event bleeding resolved.
The outcome of the event small bruises (ecchymosis) was unknown.
The outcome of the event Off label (see 2 indications) was unknown.

Quetidin 25 mg was discontinued on Jul-2024.

Concomitant medication included Dormilan (Zolpidem).

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

Causality assessment for Quetidin 25 mg
Reporter causality for the event bleeding: Not Reported
Reporter causality for the event small bruises (ecchymosis): Not Reported
Reporter causality for the event Off label (see 2 indications): Not Reported

The following information was reported:
The patient said that she was aware that she could experience these bleedings because she had read that they are side effects of the medication and in fact this year the bleeding began. The patient said that she recovered a week after she stopped taking the medication but from time to time she gets small bruises (ecchymosis).
On October 7, 2024: the new information was received from the consumer via phone from the PSP Call Center: Patient recovered a week after she stopped taking the medication but from time to time she gets small bruises (ecchymosis). Phone number and schedule for phone availability.
Concomitant product: Dormilan. No lot number and expiration date are available.

Abbott comment:
According to the local monograph: Small bruises (ecchymosis): Unexpected Bleeding: Unexpected

Follow up information was received on 10-Apr-2025.
Narrative updated.

Following information was provided.
Three follow-up attempts were made unsuccessful on the following dates:
1. 02-Jan-25
2. 17-Feb-25
3. 20-Mar-25

Continuation Sheet for CIOMS report

There is no other safety information.
Abbott Comment: Follow up 1 was received on 11-Apr-2025 and Follow up 2 which was an amendment to follow up 1 was received on 14-Apr-2025. Both follow up version were processed together.

Version 2 created on 16-Apr-2025 to amend the reporter details. No new medical information added.

Pharmacovigilance Comments :

Additional Report Source:
Patient/Consumer,Patient/Consumer,Patient/Consumer

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

Product-Reaction Level

1) Drug : Quetidin 25 mg (QUET>QUETIAPINE)
Active Substance : 1) QUETIAPINE
Drug Characterization : Suspect
Form of Admin : 1) Capsule
Lot Number : 1) Unknown
Route of Admin : 1) Oral
Indications : 1) obsessive compulsive disorder [10029898 - Obsessive-compulsive disorder]
2) anxiety [10002855 - Anxiety]
Therapy Dates : 1) From : ??-??-2020 To :??-Jul-2024
Therapy Duration : 1) 54 Months
Action(s) Taken With Drug : Drug withdrawn

Causality

1) bleeding (Bleeding - 10005103, Haemorrhage - 10055798 )
Causality as per reporter : Not Reported
Causality as per Mfr : Reasonable possibility
DeChallenge : Positive
ReChallenge : Not Applicable

2) small bruises (ecchymosis) (Ecchymosis - 10014080, Ecchymosis - 10014080 )
Causality as per reporter : Not Reported
Causality as per Mfr : No reasonable possibility
DeChallenge : Unknown
ReChallenge : Not Applicable

3) Off label (see 2 indications) (Off label use in unapproved indication - 10084345, Off label use - 10053762 )
Causality as per reporter : Not Reported
Causality as per Mfr : Not applicable
DeChallenge : Unknown
ReChallenge : Not Applicable

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

Dosage Text :
Drug 1 :QUET>QUETIAPINE
1) 2 capsules per day

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

1). Drug : Dormilan (Zolpidem)
Active Substance : 1) ZOLPIDEM
Form Strength :

23. OTHER RELEVANT HISTORY (Continuation...)

Medical History And Concurrent Conditions :
Unknown