

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY PANAMA	2. DATE OF BIRTH			2a. AGE Unk	3. SEX Female	3a. WEIGHT Unk	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION <input type="checkbox"/> PATIENT DIED <input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION <input type="checkbox"/> INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY <input type="checkbox"/> LIFE THREATENING <input type="checkbox"/> CONGENITAL ANOMALY <input type="checkbox"/> OTHER
		Day	Month	Year				Day	Month	Year	
		PRIVACY			Unk				OCT	2024	

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

Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)	Product	Serious	Listed	Reporter Causality	Company Causality
Insomnia (first episode) [Insomnia]	DAPAGLIFLOZIN, METFORMIN	No	No	Related	Related
Xigduo 5mg/1000mg for insulin resistance (off label) [Off label use]	DAPAGLIFLOZIN, METFORMIN	No	No	Related	Related

(Continued on Additional Information Page)

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1) DAPAGLIFLOZIN, METFORMIN (DAPAGLIFLOZIN, METFORMIN) Tablet (Continued on Additional Information Page)		20. DID REACTION ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
15. DAILY DOSE(S) #1) 5 milligram, qd	16. ROUTE(S) OF ADMINISTRATION #1) Oral use	
17. INDICATION(S) FOR USE #1) Insulin resistance (Insulin resistance)		21. DID REACTION REAPPEAR AFTER REINTRODUCTION? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
18. THERAPY DATES(from/to) #1) OCT-2024 / MAR-2025	19. THERAPY DURATION #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 Unknown	Type of History / Notes Indication	Description Insulin resistance (Insulin resistance)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER AstraZeneca Serban Ghiorgiu 1 Medimmune Way Gaithersburg, Maryland 20878 UNITED STATES Phone: +1 301-398-0000		26. REMARKS World Wide #: PA-ASTRAZENECA-202506CAM017494PA Study ID: PSP-23269 Case References: PA-AstraZeneca-CH-00895460A
	24b. MFR CONTROL NO. 202506CAM017494PA	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 20-JUN-2025	24d. REPORT SOURCE <input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL <input type="checkbox"/> OTHER:	NAME AND ADDRESS WITHHELD.
DATE OF THIS REPORT 24-JUN-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

24-Jun-2025 13:34

ADDITIONAL INFORMATION**7+13. DESCRIBE REACTION(S) continued**

Case Description: A solicited report has been received from a consumer in Patient Support Program. The report concerns a female patient born in 1996.

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Dapagliflozin, Metformin (dapagliflozin, metformin) 5 milligram qd, Oral use, during OCT-2024 for insulin resistance.

During 15-OCT-24, the patient experienced insomnia (first episode) (preferred term: Insomnia). On an unknown date, the patient experienced xigduo 5mg/1000mg for insulin resistance (off label) (preferred term: Off label use).
The last dose of DAPAGLIFLOZIN, METFORMIN prior to onset was taken on 15-JUN-25.

It is unknown if any action was taken with Dapagliflozin, Metformin (dapagliflozin, metformin).

The patient recovered from the event(s) insomnia (first episode). The outcome of the event(s) of xigduo 5mg/1000mg for insulin resistance (off label) was unknown.

The events were considered non-serious.

The reporter considered that there was a reasonable possibility of a causal relationship between Dapagliflozin, Metformin and the following event(s): insomnia (first episode) and xigduo 5mg/1000mg for insulin resistance (off label).

The company physician considered that there was a reasonable possibility of a causal relationship between Dapagliflozin, Metformin and the following event(s): insomnia (first episode) and xigduo 5mg/1000mg for insulin resistance (off label).

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) DAPAGLIFLOZIN, METFORMIN (DAPAGLIFLOZIN, METFORMIN) Tablet; Regimen #2	UNK; Unknown	Insulin resistance (Insulin resistance)	Unknown; Unknown