

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY GUATEMALA	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	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	Unk	Female	Unk	Day	Month	Year	
			PRIVACY						Unk		
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			
Thirst [Thirst]		DAPAGLIFLOZIN		No	No	Not Applicable		Related			
Dizziness [Dizziness]		DAPAGLIFLOZIN		No	No	Not Applicable		Related			
Urge to urinate [Micturition urgency]		DAPAGLIFLOZIN		No	No	Not Applicable		Related			
Glucose at 300 mg/dL [Blood glucose increased]		DAPAGLIFLOZIN		No	No	Not Applicable		Related			
(Continued on Additional Information Page)											

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1) DAPAGLIFLOZIN (DAPAGLIFLOZIN) Film-coated tablet		20. DID REACTION ABATE AFTER STOPPING DRUG? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
15. DAILY DOSE(S) #1) 10 milligram, qd	16. ROUTE(S) OF ADMINISTRATION #1) Oral use	
17. INDICATION(S) FOR USE #1) diabetes (Diabetes mellitus)		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) SEP-2024 / FEB-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 Unknown	Type of History / Notes Indication Historical Drug	Description Diabetes (Diabetes mellitus) metformin (Metformin)
(Continued on Additional Information Page)		

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER AstraZeneca Serban Ghiorgheu 1 Medimmune Way Gaithersburg, Maryland 20878 UNITED STATES Phone: +1 301-398-0000		26. REMARKS World Wide #: GT-ASTRAZENECA-202506CAM000590GT Study ID: PSP-23269 Case References: GT-AstraZeneca-CH-00882999A
	24b. MFR CONTROL NO. 202506CAM000590GT	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD. NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 02-JUN-2025	24d. REPORT SOURCE <input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL <input type="checkbox"/> OTHER:	
DATE OF THIS REPORT 05-JUN-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

05-Jun-2025 06:26

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)	Product	Serious	Listed	Reporter Causality	Company Causality
Urinary tract infection [Urinary tract infection]	DAPAGLIFLOZIN	No	Yes	Not Applicable	Related
Vaginal infection [Vaginal infection]	DAPAGLIFLOZIN	No	Yes	Not Applicable	Related

Case Description: A solicited report has been received from a consumer in Patient Support Program. The report concerns a female patient born in 1959.

No medical history was reported.

Past drug therapy included Metformin.

The patient started treatment with Dapagliflozin (dapagliflozin) 10 milligram qd, Oral use, during SEP-2024 for diabetes.

On an unknown date, the patient experienced vaginal infection (preferred term: Vaginal infection), urinary tract infection (preferred term: Urinary tract infection), glucose at 300 mg/dl (preferred term: Blood glucose increased), urge to urinate (preferred term: Micturition urgency), dizziness (preferred term: Dizziness) and thirst (preferred term: Thirst).

Treatment with Dapagliflozin (dapagliflozin) was discontinued during FEB-2025.

The patient recovered from the event(s) dizziness, glucose at 300 mg/dl, thirst and urge to urinate on an unspecified date. At the time of reporting, the event urinary tract infection and vaginal infection was ongoing.

The events were considered non-serious.

The reporter did not assess causality for dizziness, glucose at 300 mg/dl, thirst, urge to urinate, urinary tract infection and vaginal infection.

The company physician considered that there was a reasonable possibility of a causal relationship between Dapagliflozin and the following event(s): dizziness, glucose at 300 mg/dl, thirst, urge to urinate, urinary tract infection and vaginal infection.

Laboratory values are available.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Blood glucose 300	milligram per decilitre	

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown	Historical Drug	metformin (Metformin); Patient mentions that the first medication he took for diabetes was only metformin and that this medication alone caused him an upset stomach.