

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 checked="" type="checkbox"/> OTHER
		Day	Month	Year	Unk	Female	Unk	Day	Month	Year	
			PRIVACY						Unk		
7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data) Other Serious Criteria: Medically Significant											

Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)	Product	Serious	Listed	Reporter Causality	Company Causality
Cancer [Neoplasm malignant]	DAPAGLIFLOZIN, METFORMIN	Yes	No	Not Related	Not Related
Patients daughter mentions that the patient cant stand sitting. [Discomfort]	DAPAGLIFLOZIN, METFORMIN	No	No	Not Related	Not Related
The patients daughter indicates that she has difficulty walking. [Gait disturbance]	DAPAGLIFLOZIN, METFORMIN	No	No	Not Related	Not Related

(Continued on Additional Information Page)

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1) DAPAGLIFLOZIN, METFORMIN (DAPAGLIFLOZIN, METFORMIN) Tablet		20. DID REACTION ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" 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) Ongoing	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 Diabetes (Diabetes mellitus)

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-202505CAM021541GT Study ID: PSP-23269 Case References: GT-AstraZeneca-CH-00877812A
	24b. MFR CONTROL NO. 202505CAM021541GT	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD. NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 26-MAY-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 29-MAY-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

29-May-2025 06:23

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

Case Description: A solicited report has been received from a non-health professional in Patient Support Program. The report concerns a female patient born in 1965.

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Dapagliflozin, Metformin (dapagliflozin, metformin) 10 milligram qd, Oral use, on an unknown date for diabetes.

On an unknown date, the patient experienced cancer (preferred term: Neoplasm malignant), the patients daughter indicates that she has difficulty walking. (preferred term: Gait disturbance) and patients daughter mentions that the patient cant stand sitting. (preferred term: Discomfort).

The dose of Dapagliflozin, Metformin (dapagliflozin, metformin) was not changed.

The outcome of the event(s) of cancer, patients daughter mentions that the patient cant stand sitting. and the patients daughter indicates that she has difficulty walking. was unknown.

The following event(s) were considered serious due to medically significant:cancer.

The following events were considered non-serious:patients daughter mentions that the patient cant stand sitting. and the patients daughter indicates that she has difficulty walking..

The reporter did not consider that there was a reasonable possibility of a causal relationship between Dapagliflozin, Metformin and the following event(s): cancer, patients daughter mentions that the patient cant stand sitting. and the patients daughter indicates that she has difficulty walking..

The company physician did not consider that there was a reasonable possibility of a causal relationship between Dapagliflozin, Metformin and the following event(s): cancer, patients daughter mentions that the patient cant stand sitting. and the patients daughter indicates that she has difficulty walking..