

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY COSTA RICA	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		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			<input type="checkbox"/> PATIENT DIED
Patient indicates that he has depression [Depression]		FORXIGA		No	No	Not Applicable		Related			<input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
Patient indicates that he feels ill [Illness]		FORXIGA		No	No	Not Applicable		Related			<input type="checkbox"/> INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY
Patient comments that he no longer knows where she keeps things [Memory impairment]		FORXIGA		No	No	Not Applicable		Related			<input type="checkbox"/> LIFE THREATENING
(Continued on Additional Information Page)											<input type="checkbox"/> CONGENITAL ANOMALY
											<input type="checkbox"/> OTHER

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1) FORXIGA (DAPAGLIFLOZIN) Film-coated tablet		20. DID REACTION ABATE AFTER STOPPING DRUG?
15. DAILY DOSE(S) #1) 10 milligram, unknown frequency	16. ROUTE(S) OF ADMINISTRATION #1) Oral use	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
17. INDICATION(S) FOR USE #1) Unknown		21. DID REACTION REAPPEAR AFTER REINTRODUCTION?
18. THERAPY DATES(from/to) #1) Unknown	19. THERAPY DURATION #1) Unknown	<input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA

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 Procedure	Description Kidney transplant (Renal transplant)

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 #: CR-ASTRAZENECA-202505CAM013274CR Study ID: PSP-23269 Case References: CR-AstraZeneca-CH-00871724A
	24b. MFR CONTROL NO. 202505CAM013274CR	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 15-MAY-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 20-MAY-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

20-May-2025 07:25

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 (age not provided).

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Forxiga (dapagliflozin) 10 milligram, Oral use, on an unknown date.

On an unknown date, the patient experienced patient indicates that he has depression (preferred term: Depression), patient comments that he no longer knows where she keeps things (preferred term: Memory impairment) and patient indicates that he feels ill (preferred term: Illness).

It is unknown if any action was taken with Forxiga (dapagliflozin).

The outcome of the event(s) of patient comments that he no longer knows where she keeps things, patient indicates that he feels ill and patient indicates that he has depression was unknown.

The events were considered non-serious.

The reporter did not assess causality for patient comments that he no longer knows where she keeps things, patient indicates that he feels ill and patient indicates that he has depression.

The company physician considered that there was a reasonable possibility of a causal relationship between Forxiga and the following event(s): patient comments that he no longer knows where she keeps things, patient indicates that he feels ill and patient indicates that he has depression.