

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				Day	Month	Year	
		PRIVACY			Unk	Male	Unk		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]		FORXIGA		Yes	No	Not Related	Not Related				<input type="checkbox"/> PATIENT DIED <input checked="" 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
(Continued on Additional Information Page)											

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1) FORXIGA (DAPAGLIFLOZIN) Film-coated tablet {Lot # TPO170; Exp.Dt. DEC-2026}		20. DID REACTION ABATE AFTER STOPPING DRUG?
15. DAILY DOSE(S) #1) 10 milligram, qd	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) Sugar (Blood glucose increased)		21. DID REACTION REAPPEAR AFTER REINTRODUCTION?
18. THERAPY DATES(from/to) #1) Ongoing	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 06-MAY-2024 to Unknown	Type of History / Notes Indication Procedure	Description Sugar blood increased (Blood glucose increased) Surgery (Surgery)

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 #: CR-ASTRAZENECA-202506CAM019386CR Study ID: PSP-23269 Case References: CR-AstraZeneca-CH-00896801A
	24b. MFR CONTROL NO. 202506CAM019386CR	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 23-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 25-JUN-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

25-Jun-2025 15:33

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 male patient born in 1957.

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Forxiga (dapagliflozin) (batch number(s) TPO170) (expiration date(s) DEC-2026) 10 milligram qd, Oral use, on an unknown date for sugar.

On an unknown date, the patient experienced cancer (preferred term: Neoplasm malignant).

The outcome of the event(s) of cancer was unknown.

The event was considered serious (Medically Significant and Hospitalized).

The reporter did not consider that there was a reasonable possibility of a causal relationship between Forxiga and the following event (s): cancer.

The company physician did not consider that there was a reasonable possibility of a causal relationship between Forxiga and the following event(s): cancer.