

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 <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
Forxiga didnt control patient sugar [Blood glucose abnormal]	FORXIGA	No	No	Not Applicable	Not Related
Forxiga 10 mg two times a day (off-label) [Off label use]	FORXIGA	No	No	Not Applicable	Not Applicable

(Continued on Additional Information Page)

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? <input 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)		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) Unknown	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.) <table border="1"> <thead> <tr> <th>From/To Dates</th> <th>Type of History / Notes</th> <th>Description</th> </tr> </thead> <tbody> <tr> <td>Unknown to Ongoing</td> <td>Indication</td> <td>Diabetes (Diabetes)</td> </tr> </tbody> </table>			From/To Dates	Type of History / Notes	Description	Unknown to Ongoing	Indication	Diabetes (Diabetes)
From/To Dates	Type of History / Notes	Description						
Unknown to Ongoing	Indication	Diabetes (Diabetes)						

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-202507CAM025236CR Study ID: PSP-23269 Case References: CR-AstraZeneca-CH-00920922A
	24b. MFR CONTROL NO. 202507CAM025236CR	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD. NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 29-JUL-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 30-JUL-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

30-Jul-2025 23:18

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 1966.

No medical history was reported.

No concomitant products were reported.

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

On an unknown date, the patient experienced forxiga didnt control patient sugar (preferred term: Blood glucose abnormal) and forxiga 10 mg two times a day (off-label) (preferred term: Off label use).

The report described off-label use for Forxiga. The reported term was forxiga 10 mg two times a day (off-label) (preferred term: Off label use).

At the time of reporting, the event forxiga 10 mg two times a day (off-label) and forxiga didnt control patient sugar was improving.

The events were considered non-serious.

The reporter did not assess causality for forxiga 10 mg two times a day (off-label) and forxiga didnt control patient sugar. The company physician did not consider that there was a reasonable possibility of a causal relationship between Forxiga and the following event(s): forxiga didnt control patient sugar.

Laboratory values are available.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Blood glucose Blood glucose abnormal		