

# SUSPECT ADVERSE REACTION REPORT

## I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) <b>PRIVACY</b>	1a. COUNTRY <b>COSTA RICA</b>	2. DATE OF BIRTH			2a. AGE <b>65</b> Years	3. SEX <b>Female</b>	3a. WEIGHT <b>Unk</b>	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				Day	Month	Year	
			<b>PRIVACY</b>					<b>25</b>	<b>JUL</b>	<b>2025</b>	
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
HIGH SUGAR. [Blood glucose increased]	FORXIGA	Yes	No	Related	Not Related
HIGH SUGAR. [Blood glucose increased]	XIGDUO	Yes	No	Unknown	Unknown
Sentirse mal [Feeling abnormal]	FORXIGA	No	No	Unknown	Unknown
Sentirse mal [Feeling abnormal]	XIGDUO	No	No	Unknown	Unknown
Creatinina alta [Blood creatinine increased]	FORXIGA	No	No	Unknown	Unknown

(Continued on Additional Information Page)

## II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1 ) FORXIGA (DAPAGLIFLOZIN) Film-coated tablet {Lot # WH0134; Exp.Dt. OCT-2026} #2 ) XIGDUO (DAPAGLIFLOZIN, METFORMIN) Tablet {Lot # UNK}		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 #2 ) 10 milligram, qd	16. ROUTE(S) OF ADMINISTRATION #1 ) Oral use #2 ) Unknown	
17. INDICATION(S) FOR USE #1 ) Diabetes (Diabetes mellitus) #2 ) Unknown		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 ) 16-JUL-2025 / 28-JUL-2025 #2 ) Unknown	19. THERAPY DURATION #1 ) 13 days #2 ) 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 to Ongoing	Type of History / Notes Indication	Description Diabetes (Diabetes mellitus)

## IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER AstraZeneca Serban Ghiorghe 1 Medimmune Way Gaithersburg, Maryland 20878 UNITED STATES Phone: +1 301-398-0000		26. REMARKS World Wide #: CR-ASTRAZENECA-202508CAM002557CR Study ID: PSP-23269 Case References: CR-AstraZeneca-CH-00925206A
	24b. MFR CONTROL NO. <b>202508CAM002557CR</b>	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.  NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER <b>12-AUG-2025</b>	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 <b>13-AUG-2025</b>	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> FOLLOWUP: 1	

13-Aug-2025 17:05

**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
Creatinina alta [Blood creatinine increased]	XIGDUO	No	No	Unknown	Unknown
Afectación en riñones [Renal disorder]	FORXIGA	No	No	Unknown	Unknown
Afectación en riñones [Renal disorder]	XIGDUO	No	No	Unknown	Unknown
Azúcar alta [Blood glucose increased]	FORXIGA	No	No	Related	Related
Azúcar alta [Blood glucose increased]	XIGDUO	No	No	Unknown	Unknown

Case Description: A solicited report has been received from a consumer in Patient Support Program concerning a female elderly patient born in 1960 (age 65 years).

No medical history was reported. No concomitant products were reported.

The patient started treatment with Forxiga (dapagliflozin) (batch number(s) WH0134) (expiration date(s) OCT-2026) 10 milligram qd, Oral use, on 16-JUL-2025 for diabetes.

On 25-JUL-25, the patient experienced high sugar. (preferred term: Blood glucose increased).  
The last dose of FORXIGA prior to onset was taken on 28-JUL-25.

Treatment with Forxiga was discontinued on 28-JUL-2025.

The patient recovered from the event(s) high sugar. on an unspecified date.

The event was considered serious (Medically Significant).

The reporter considered that there was a reasonable possibility of a causal relationship between Forxiga and the following event(s): high sugar..

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

Laboratory values are available.

Company Clinical Comment: Blood glucose increased is not listed in the company core data sheet of dapagliflozin. Underlying diabetes mellitus along with age of patient could be contributory to the event. Due to limited information on relevant medical history, circumstances surrounding the event, aetiological and diagnostic workup, therapy compliance, concurrent diseases, concomitant medications, risk factors, family history, the evaluation did not find evidence to suggest a causal relationship between the event and the suspect drug.

**13. Lab Data**

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Blood glucose 123		