

# 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	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	
			<b>PRIVACY</b>						<b>Unk</b>		
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
Diarrhea [Diarrhoea]	XIGDUO	No	Yes	Related	Related
Dehydration [Dehydration]	XIGDUO	No	No	Related	Related

(Continued on Additional Information Page)

## II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1 ) XIGDUO (DAPAGLIFLOZIN, METFORMIN) Tablet {Lot # Unknown}		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	16. ROUTE(S) OF ADMINISTRATION #1 ) Oral use	
17. INDICATION(S) FOR USE #1 ) Unknown		21. DID REACTION REAPPEAR AFTER REINTRODUCTION?  <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
18. THERAPY DATES(from/to) #1 ) JAN-2025 / MAR-2025	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="0"> <tr> <td>From/To Dates</td> <td>Type of History / Notes</td> <td>Description</td> </tr> <tr> <td>Unknown</td> <td>Indication</td> <td>Diabetes (Diabetes mellitus)</td> </tr> </table>			From/To Dates	Type of History / Notes	Description	Unknown	Indication	Diabetes (Diabetes mellitus)
From/To Dates	Type of History / Notes	Description						
Unknown	Indication	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-202505CAM026797CR Study ID: PSP-23269 Case References: CR-AstraZeneca-CH-00881670A
	24b. MFR CONTROL NO. <b>202505CAM026797CR</b>	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.  NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER <b>30-MAY-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>03-JUN-2025</b>	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

03-Jun-2025 08:25

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**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 1977.

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Xigduo (dapagliflozin, metformin) (batch number(s) Unknown) 10 milligram qd, Oral use, during JAN-2025.

On an unknown date, the patient experienced diarrhea (preferred term: Diarrhoea) and dehydration (preferred term: Dehydration).

Treatment with Xigduo (dapagliflozin, metformin) was discontinued during MAR-2025.

The patient recovered from the event(s) dehydration and diarrhea on an unspecified date.

The events were considered non-serious.

The reporter considered that there was a reasonable possibility of a causal relationship between Xigduo and the following event(s): dehydration and diarrhea.

The company physician considered that there was a reasonable possibility of a causal relationship between Xigduo and the following event(s): dehydration and diarrhea.