

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
No adverse event [No adverse event]	XIGDUO	No	No	Not Applicable	Not Applicable

(Continued on Additional Information Page)

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1) XIGDUO (DAPAGLIFLOZIN, METFORMIN) Tablet {Lot # Unknown} (Continued on Additional Information Page)		20. DID REACTION ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" 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) Prediabetes (Glucose tolerance impaired) (Continued on Additional Information Page)		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) Ongoing	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.)		
From/To Dates Unknown to Ongoing	Type of History / Notes Indication	Description Kidney disorder (Renal disorder)
Unknown to Ongoing	Indication	Prediabetes (Glucose tolerance impaired)

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-202507CAM009041CR Study ID: PSP-23269 Case References: CR-AstraZeneca-CH-00909388A
	24b. MFR CONTROL NO. 202507CAM009041CR	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 11-JUL-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 16-JUL-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

16-Jul-2025 05:14

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 Xigduo (dapagliflozin, metformin) (batch number(s) Unknown) 10 milligram qd, Oral use, on an unknown date for kidney problems and prediabetes.

There was no adverse event for Xigduo described in the report.

The dose of Xigduo (dapagliflozin, metformin) was not changed.

The outcome of the event(s) of no adverse event was unknown.

The event was considered non-serious.

The reporter did not assess causality for no adverse event.

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#1) XIGDUO (DAPAGLIFLOZIN, METFORMIN) Tablet {Lot # Unknown}; Regimen #1	10 milligram, qd; Oral use	Prediabetes (Glucose tolerance impaired) Kidney problems (Renal disorder)	Ongoing; Unknown