

# 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
		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				
The pharmacy dispensed Xigduo 10mg/1000mg instead of Xigduo 5mg/1000mg (medication error). [Product dispensing error]		XIGDUO		No	No	Not Applicable	Not Applicable				
(Continued on Additional Information Page)											<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

## 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?
(Continued on Additional Information Page)		
15. DAILY DOSE(S) #1 ) 5mg/1000mg	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 ) Diabetes (Diabetes mellitus)		21. DID REACTION REAPPEAR AFTER REINTRODUCTION?
18. THERAPY DATES(from/to) #1 ) Unknown	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	Type of History / Notes Indication	Description 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-202507CAM014041CR Study ID: PSP-23269 Case References: CR-AstraZeneca-CH-00912904A
	24b. MFR CONTROL NO. <b>202507CAM014041CR</b>	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER <b>17-JUL-2025</b>	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 <b>22-JUL-2025</b>	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

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 1956.

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Xigduo (dapagliflozin, metformin) (batch number(s) Unknown) 5 milligram qd, Oral use, on an unknown date for diabetes.

On an unknown date, the patient experienced the pharmacy dispensed xigduo 10mg/1000mg instead of xigduo 5mg/1000mg (medication error). (preferred term: Product dispensing error).

The outcome of the event(s) of the pharmacy dispensed xigduo 10mg/1000mg instead of xigduo 5mg/1000mg (medication error). was unknown.

The event was considered non-serious.

The reporter did not assess causality for the pharmacy dispensed xigduo 10mg/1000mg instead of xigduo 5mg/1000mg (medication error)..

This case was marked as suppressed due to Medication Error with no AE.

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; Regimen #2	10mg/1000mg; Oral use	Diabetes (Diabetes mellitus)	Unknown; Unknown