

# 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	Male	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
XIGDUO 10mg/1000mg dos pastillas al día (uso no aprobado) [Off label use]	XIGDUO	No	No	Not Related	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 # WK0052; Exp.Dt. JUN-2026}		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, bid	16. ROUTE(S) OF ADMINISTRATION #1 ) Oral use	
17. INDICATION(S) FOR USE #1 ) Diabetes (Diabetes mellitus)		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</td> <td>Indication</td> <td>Diabetes (Diabetes)</td> </tr> </tbody> </table>			From/To Dates	Type of History / Notes	Description	Unknown	Indication	Diabetes (Diabetes)
From/To Dates	Type of History / Notes	Description						
Unknown	Indication	Diabetes (Diabetes)						

## IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER AstraZeneca Serban Ghiorghiu 1 Medimmune Way Gaithersburg, Maryland 20878 UNITED STATES Phone: +1 301-398-0000		26. REMARKS World Wide #: CR-ASTRAZENECA-202508CAM011912CR Study ID: PSP-23269 Case References: CR-AstraZeneca-CH-00932159A
	24b. MFR CONTROL NO. <b>202508CAM011912CR</b>	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.  NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER <b>16-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>20-AUG-2025</b>	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

20-Aug-2025 08:20

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**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 male elderly patient born in 1952.

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Xigduo (dapagliflozin, metformin) (batch number(s) WK0052) (expiration date(s) JUN-2026) 10 milligram bid, Oral use, on an unknown date for diabetes.

On an unknown date, the patient experienced xigduo 10mg/1000mg dos pastillas al día (uso no aprobado) (preferred term: Off label use).

The report described off-label use for Xigduo. The reported term was xigduo 10mg/1000mg dos pastillas al día (uso no aprobado) (preferred term: Off label use).

It is unknown if any action was taken with Xigduo (dapagliflozin, metformin).

The outcome of the event(s) of xigduo 10mg/1000mg dos pastillas al día (uso no aprobado) was unknown.

The event was considered non-serious.

The reporter did not consider that there was a reasonable possibility of a causal relationship between Xigduo and the following event (s): xigduo 10mg/1000mg dos pastillas al día (uso no aprobado).