

## 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
Patient indicates that the medication Xigduo 5mg/1000mg had no effect on him [Drug ineffective]	XIGDUO	No	No	Not Applicable	Not Applicable
Patient indicates that the medication Xigduo 5mg/1000mg had no effect on him [Drug ineffective]	XIGDUO	No	No	Not Applicable	Not Applicable
Patient comments that he consumes 2 daily doses of Xigduo 10mg/1000mg [Off label use]	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 #2 ) XIGDUO (DAPAGLIFLOZIN, METFORMIN) Tablet		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 ) 5 milligram #2 ) 10 milligram, bid	16. ROUTE(S) OF ADMINISTRATION #1 ) Oral use #2 ) Oral use	
17. INDICATION(S) FOR USE #1 ) Type II Diabetes (Type 2 diabetes mellitus) #2 ) Type II Diabetes (Type 2 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 #2 ) Ongoing	19. THERAPY DURATION #1 ) Unknown #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 Type II diabetes mellitus (Type 2 diabetes mellitus)

## IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER AstraZeneca Serban Ghiorguiu 1 Medimmune Way Gaithersburg, Maryland 20878 UNITED STATES Phone: +1 301-398-0000		26. REMARKS World Wide #: CR-ASTRAZENECA-202504CAM025600CR Study ID: PSP-23269 Case References: CR-AstraZeneca-CH-00859129A
	24b. MFR CONTROL NO. <b>202504CAM025600CR</b>	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.  NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER <b>29-APR-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>07-MAY-2025</b>	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

07-May-2025 07:19

**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
Patient comments that he consumes 2 daily doses of Xigduo 10mg/1000mg [Off label use]	XIGDUO	No	No	Not Applicable	Not Applicable

Case Description: A solicited report has been received from a consumer in Patient Support Program. The report concerns a male patient (age not provided).

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Xigduo (dapagliflozin, metformin) 5 milligram, Oral use, on an unknown date for type ii diabetes and with Xigduo (dapagliflozin, metformin) 10 milligram bid, Oral use, on an unknown date for type ii diabetes.

On an unknown date, the patient experienced patient indicates that the medication xigduo 5mg/1000mg had no effect on him (preferred term: Drug ineffective) and patient comments that he consumes 2 daily doses of xigduo 10mg/1000mg (preferred term: Off label use).

The report described off-label use for Xigduo. The reported term was patient comments that he consumes 2 daily doses of xigduo 10mg/1000mg (preferred term: Off label use). The report described lack of effect for Xigduo, Xigduo. The reported term was "patient indicates that the medication xigduo 5mg/1000mg had no effect on him" (preferred term: Drug ineffective).

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

The outcome of the event(s) of patient comments that he consumes 2 daily doses of xigduo 10mg/1000mg and patient indicates that the medication xigduo 5mg/1000mg had no effect on him was unknown.

The events were considered non-serious.

The reporter did not assess causality for patient comments that he consumes 2 daily doses of xigduo 10mg/1000mg and patient indicates that the medication xigduo 5mg/1000mg had no effect on him.

This case was marked as suppressed due to Lack of Efficacy with no AE.