

# 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 <b>35</b> Years	3. SEX <b>Female</b>	3a. WEIGHT <b>Unk</b>	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year				Day	Month	Year	
			<b>PRIVACY</b>					<b>08</b>	<b>JUL</b>	<b>2025</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
Intestinal discomfort [Abdominal discomfort]	DAPAGLIFLOZIN, METFORMIN	No	Yes	Related	Related
Diarrhea [Diarrhoea]	DAPAGLIFLOZIN, METFORMIN	No	Yes	Related	Related
Stomach pain [Abdominal pain upper]	DAPAGLIFLOZIN, METFORMIN	No	Yes	Related	Related
Xigduo 10mg/1000mg for insulin resistance (off-label) [Off label use]	DAPAGLIFLOZIN, METFORMIN	No	No	Not Applicable	Not Applicable

(Continued on Additional Information Page)

☐ PATIENT DIED  
☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION  
☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY  
☐ LIFE THREATENING  
☐ CONGENITAL ANOMALY  
☐ OTHER

## II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) <b>#1 ) DAPAGLIFLOZIN, METFORMIN (DAPAGLIFLOZIN, METFORMIN) Tablet</b>		20. DID REACTION ABATE AFTER STOPPING DRUG?  <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
15. DAILY DOSE(S) <b>#1 ) 10 milligram, qd</b>	16. ROUTE(S) OF ADMINISTRATION <b>#1 ) Oral use</b>	
17. INDICATION(S) FOR USE <b>#1 ) Insulin resistance (Insulin resistance)</b>		21. DID REACTION REAPPEAR AFTER REINTRODUCTION?  <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
18. THERAPY DATES(from/to) <b>#1 ) 08-JUL-2025 / Unknown</b>	19. THERAPY DURATION <b>#1 ) Unknown</b>	

## 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      Type of History / Notes      Description Unknown to Ongoing      Indication      Insulin resistance (Insulin resistance)		

## IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER <b>AstraZeneca Serban Ghiorghiu 1 Medimmune Way Gaithersburg, Maryland 20878 UNITED STATES Phone: +1 301-398-0000</b>		26. REMARKS <b>World Wide #: CR-ASTRAZENECA-202507CAM022334CR Study ID: PSP-23269 Case References: CR-AstraZeneca-CH-00918896A</b>
	24b. MFR CONTROL NO. <b>202507CAM022334CR</b>	25b. NAME AND ADDRESS OF REPORTER <b>NAME AND ADDRESS WITHHELD.</b>  <b>NAME AND ADDRESS WITHHELD.</b>
24c. DATE RECEIVED BY MANUFACTURER <b>25-JUL-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>28-JUL-2025</b>	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

28-Jul-2025 21:23

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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 female adult patient born in 1990 (age 35 years).

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Dapagliflozin, Metformin (dapagliflozin, metformin) 10 milligram qd, Oral use, on 08-JUL-2025 for insulin resistance.

On 08-JUL-25, the patient experienced xigduo 10mg/1000mg for insulin resistance (off-label) (preferred term: Off label use). On 10-JUL-25, the patient experienced intestinal discomfort (preferred term: Abdominal discomfort). On 12-JUL-25, the patient experienced diarrhea (preferred term: Diarrhoea) and stomach pain (preferred term: Abdominal pain upper).

At the time of reporting, the event diarrhea, intestinal discomfort and stomach pain was improving. The outcome of the event(s) of xigduo 10mg/1000mg for insulin resistance (off-label) was unknown.

The events were considered non-serious.

The reporter did not assess causality for xigduo 10mg/1000mg for insulin resistance (off-label). The reporter considered that there was a reasonable possibility of a causal relationship between Dapagliflozin, Metformin and the following event(s): diarrhea, intestinal discomfort and stomach pain.

The company physician considered that there was a reasonable possibility of a causal relationship between Dapagliflozin, Metformin and the following event(s): diarrhea, intestinal discomfort and stomach pain.