

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
		Day	Month	Year				Day	Month	Year	
		PRIVACY			Unk	Female	Unk		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
Low blood sugar [Blood glucose decreased]	XIGDUO	No	No	Related	Related
Low blood sugar [Blood glucose decreased]	Disfruto Mi Salud Biopharma/Oncology/Immunology/Rare Diseases	No	No	Related	Related
Underweight/she lost weight [Underweight]	XIGDUO	No	No	Related	Related

(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) #1) XIGDUO (DAPAGLIFLOZIN, METFORMIN) Tablet {Lot # Unknown} #2) Disfruto Mi Salud Biopharma/Oncology/Immunology/Rare Diseases (Continued on Additional Information Page)		20. DID REACTION ABATE AFTER STOPPING DRUG? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
15. DAILY DOSE(S) #1) 10 milligram, qd #2) Unknown	16. ROUTE(S) OF ADMINISTRATION #1) Oral use #2) Unknown	
17. INDICATION(S) FOR USE #1) blood sugar abnormal (Blood glucose abnormal) #2) Unknown		21. DID REACTION REAPPEAR AFTER REINTRODUCTION? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
18. THERAPY DATES(from/to) #1) JUN-2024 / Unknown #2) Unknown	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.) <table border="1"> <thead> <tr> <th>From/To Dates</th> <th>Type of History / Notes</th> <th>Description</th> </tr> </thead> <tbody> <tr> <td>JUN-2024 to Unknown</td> <td>Historical Drug</td> <td></td> </tr> <tr> <td>Unknown to Ongoing</td> <td>Indication</td> <td>Diabetes (Diabetes mellitus)</td> </tr> </tbody> </table>			From/To Dates	Type of History / Notes	Description	JUN-2024 to Unknown	Historical Drug		Unknown to Ongoing	Indication	Diabetes (Diabetes mellitus)
From/To Dates	Type of History / Notes	Description									
JUN-2024 to Unknown	Historical Drug										
Unknown to Ongoing	Indication	Diabetes (Diabetes mellitus)									

(Continued on Additional Information Page)

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-202505CAM012212CR Study ID: PSP-23269 Case References: CR-AstraZeneca-CH-00871065A
	24b. MFR CONTROL NO. 202505CAM012212CR	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 15-MAY-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 17-MAY-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

17-May-2025 08:22

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
Underweight/she lost weight [Underweight]	Disfruto Mi Salud Biopharma/Oncology/Immunology/Rare Diseases	No	No	Related	Not Related
Memory is not doing so well [Memory impairment]	XIGDUO	No	No	Unknown	Related
Memory is not doing so well [Memory impairment]	Disfruto Mi Salud Biopharma/Oncology/Immunology/Rare Diseases	No	No	Unknown	Not Related

Case Description: A solicited report has been received from a non-health professional in Patient Support Program. The report concerns a female patient born in 1955.

The patient's past and current medical history included hand problems (dates not reported), knee pain (dates not reported) and neuropathy (dates not reported).

Past drug therapy included.

The patient started treatment with Xigduo (dapagliflozin, metformin) (batch number(s) Unknown) 10 milligram qd, Oral use, during JUN-2024 for blood sugar abnormal and with Disfruto Mi Salud Biopharma/Oncology/Immunology/Rare Diseases (disfruto mi salud biopharma/oncology/immunology/rare diseases), on an unknown date.

On an unknown date, the patient experienced low blood sugar (preferred term: Blood glucose decreased), memory is not doing so well (preferred term: Memory impairment) and underweight/she lost weight (preferred term: Underweight).

It is unknown if any action was taken with Disfruto Mi Salud Biopharma/Oncology/Immunology/Rare Diseases (disfruto mi salud biopharma/oncology/immunology/rare diseases).

The patient recovered from the event(s) low blood sugar and underweight/she lost weight on an unspecified date. The outcome of the event(s) of memory is not doing so well was unknown.

The events were considered non-serious.

The reporter did not assess causality for memory is not doing so well. The reporter considered that there was a reasonable possibility of a causal relationship between Disfruto Mi Salud Biopharma/Oncology/Immunology/Rare Diseases and the following event(s): low blood sugar and underweight/she lost weight . The reporter considered that there was a reasonable possibility of a causal relationship between Xigduo and the following event(s): low blood sugar and underweight/she lost weight . The company physician did not consider that there was a reasonable possibility of a causal relationship between Disfruto Mi Salud Biopharma/Oncology/Immunology/Rare Diseases and the following event(s): memory is not doing so well and underweight/she lost weight . The company physician considered that there was a reasonable possibility of a causal relationship between Disfruto Mi Salud Biopharma/Oncology/Immunology/Rare Diseases and the following event(s): low blood sugar. The company physician considered that there was a reasonable possibility of a causal relationship between Xigduo and the following event(s): low blood sugar, memory is not doing so well and underweight/she lost weight .

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
#2) Disfruto Mi Salud Biopharma/Oncology/Immunology/Rare Diseases (Disfruto Mi Salud Biopharma/Oncology/Immunology/Rare Diseases) Concentrate for solution for infusion; Regimen #1	Unknown; Unknown	Unknown	Unknown; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
JUN-2024 to Unknown	Historical Drug	Xigduo; Drug Indication: Product used for unknown indication (Product used for unknown indication)
Unknown	Historical Condition	Neuropathy (Neuropathy peripheral);
Unknown	Historical Condition	Knee pain (Arthralgia);
Unknown	Historical Condition	Hand pain (Pain in extremity);

17-May-2025 08:22

ADDITIONAL INFORMATION

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown	Indication	Blood sugar abnormal (Blood glucose abnormal);