

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY COSTA RICA	2. DATE OF BIRTH			2a. AGE 56 Years	3. SEX Female	3a. WEIGHT Unk	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year				Day	Month	Year	
			PRIVACY						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
Urinary tract infection [Urinary tract infection]	XIGDUO	No	Yes		

(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		20. DID REACTION ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
15. DAILY DOSE(S) #1) UNK	16. ROUTE(S) OF ADMINISTRATION #1) Unknown	
17. INDICATION(S) FOR USE #1) (Not Coded)		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.)		
From/To Dates	Type of History / Notes	Description
Unknown		

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER AstraZeneca Serban Gheorghiu 1 Medimmune Way Gaithersburg, Maryland 20878 UNITED STATES Phone: +1 301-398-0000		26. REMARKS World Wide #: CR-ASTRAZENECA-202507CAM015307CR
	24b. MFR CONTROL NO. 202507CAM015307CR	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 18-JUL-2025	24d. REPORT SOURCE <input type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL <input checked="" type="checkbox"/> OTHER: Spontaneous	
DATE OF THIS REPORT 23-JUL-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

23-Jul-2025 04:18

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Case Description: A spontaneous report has been received from a consumer. The report concerns a female adult patient (age 56 years).

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Xigduo (dapagliflozin, metformin) UNK, on an unknown date.

On an unknown date, the patient experienced urinary tract infection (preferred term: Urinary tract infection).

The outcome of the event(s) of urinary tract infection was unknown.

The event was considered non-serious.