SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET Day	Month	Year
PRIVACY	COSTA RICA		PRIVACY		Unk	Male	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
Patient was decompensated [Feeling abnormal]	XIGDUO	No	No	Not Applicable	Related
Uso Off-Label [Off label use]	XIGDUO	No	No	Not Applicable	Not Applicable

(Continued on Additional Information Page)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ 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 # WK0052; Exp.Dt. JUN-2026}

20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☒ NA

15. DAILY DOSE(S)
#1) 10mg/1000mg

16. ROUTE(S) OF ADMINISTRATION
#1) Oral use

17. INDICATION(S) FOR USE
#1) Diabetes (Diabetes mellitus)

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☒ NA

18. THERAPY DATES(from/to)
#1) Ongoing

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 to Ongoing	Indication	Diabetes (Diabetes mellitus)
Unknown	Historical Condition	Liver disorder (Liver disorder)

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-202409CAM008919CR
Case References: CR-AstraZeneca-CH-00709851A

24b. MFR CONTROL NO.
202409CAM008919CR

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.

NAME AND ADDRESS WITHHELD.

24c. DATE RECEIVED BY MANUFACTURER
07-MAY-2025

24d. REPORT SOURCE
☒ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL ☐ OTHER:

DATE OF THIS REPORT
13-MAY-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

Mfr. Control Number: 202409CAM008919CR

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 patient born in 1969.

The patient’s past and current medical history included kidney disorder (dates not reported) and liver disorder (dates not 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 patient was decompensated (preferred term: Feeling abnormal) and uso off-label (preferred term: Off label use).

The report described off-label use for Xigduo. The reported term was uso off-label (preferred term: Off label use).

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

The outcome of the event(s) of patient was decompensated and uso off-label was unknown.

The events were considered non-serious.

The reporter did not assess causality for patient was decompensated and uso off-label.
The company physician considered that there was a reasonable possibility of a causal relationship between Xigduo and the following event(s): patient was decompensated.

Summary of follow-up information received by AstraZeneca on 07-May-2025: Event Off-Label use added. Action taken updated from Withdrawn to No Change. Patient medical history added. Consent to FU with reporter updated as Yes, Suppress automated follow-up updated as No. Suspect product Xigduo 1 dosage regimens updated to one regimen, indication, frequency and expiration date added. Suspect product Xigduo 2 removed. Narrative updated.

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown	Historical Condition	Kidney disorder (Renal disorder);