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	DOMINICAN REPUBLIC		PRIVACY		70 Years	Female	Unk	02	JUN	2025

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 IS SERIOUSLY ILL [Illness]	XIGDUO	No	No	Not Related	Not Related
PATIENT'S BLOOD PRESSURE ROSE [Blood pressure increased]	XIGDUO	No	No	Not Related	Not Related
PATIENT'S SUGAR LEVEL ROSE [Blood glucose increased]	XIGDUO	No	No	Not Related	Not Related
PATIENT TAKES XIGDUO 10MG/1000MG FOR HYPERTENSION [Product use issue]	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}
(Continued on Additional Information Page)

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

15. DAILY DOSE(S)
#1) 10 milligram, qd

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

17. INDICATION(S) FOR USE
#1) Diabetes (Diabetes mellitus)
(Continued on Additional Information Page)

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☒ 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 to Ongoing	Current Condition	Blood pressure (Blood pressure measurement)
Unknown to Ongoing	Indication	Diabetes (Diabetes mellitus)

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 #: DO-ASTRAZENECA-202506CAM000604DO
Study ID: PSP-23269
Case References: DO-AstraZeneca-CH-00883021A

24b. MFR CONTROL NO.
202506CAM000604DO

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

NAME AND ADDRESS WITHHELD.

24c. DATE RECEIVED BY MANUFACTURER
02-JUN-2025

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

DATE OF THIS REPORT
05-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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 elderly patient born in 1954 (age 70 years).

The patient’s past and current medical history included blood pressure (ongoing).

No concomitant products were reported.

The patient started treatment with Xigduo (dapagliflozin, metformin) (batch number(s) wk0052) (expiration date(s) JUN-2026) 10 milligram qd, Oral use, on an unknown date for diabetes and hypertension.

On 02-JUN-25, the patient experienced patient's blood pressure rose (preferred term: Blood pressure increased) and patient's sugar level rose (preferred term: Blood glucose increased). On an unknown date, the patient experienced patient is seriously ill (preferred term: Illness) and patient takes xigduo 10mg/1000mg for hypertension (preferred term: Product use issue).

The report described off-label use for Xigduo.

It is unknown if any action was taken with Xigduo (dapagliflozin, metformin).

The outcome of the event(s) of patient is seriously ill, patient takes xigduo 10mg/1000mg for hypertension, patient's blood pressure rose and patient's sugar level rose was unknown.

The events were considered non-serious.

The reporter did not assess causality for patient takes xigduo 10mg/1000mg for hypertension.The reporter did not consider that there was a reasonable possibility of a causal relationship between Xigduo and the following event(s): patient is seriously ill, patient's blood pressure rose and patient's sugar level rose.
The company physician did not consider that there was a reasonable possibility of a causal relationship between Xigduo and the following event(s): patient is seriously ill, patient's blood pressure rose and patient's sugar level rose.

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
#1) XIGDUO (DAPAGLIFLOZIN, METFORMIN) Tablet {Lot # wk0052; Exp.Dt. JUN-2026}; Regimen #1	10 milligram, qd; Oral use	Diabetes (Diabetes mellitus) Hypertension (Hypertension)	Unknown; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Indication	Hypertension (Hypertension);