SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET		
		Day	Month	Year				Day	Month	Year
PRIVACY	COSTA RICA		PRIVACY		Unk	Male	Unk		Unk	

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)

Other Serious Criteria: Medically Significant

Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)	Product	Serious	Listed	Reporter Causality	Company Causality
Patient has been decompensated [Diabetic metabolic decompensation]	DAPAGLIFLOZIN, METFORMIN	Yes	No	Not Applicable	Not Related
Schizophrenia [Schizophrenia]	DAPAGLIFLOZIN, METFORMIN	Yes	No	Not Applicable	Related
Cerebral palsy [Cerebral palsy]	DAPAGLIFLOZIN, METFORMIN	Yes	No	Not Applicable	Related

(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) DAPAGLIFLOZIN, METFORMIN (DAPAGLIFLOZIN, METFORMIN) Tablet

15. DAILY DOSE(S)
#1) 10 milligram, q12h

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

17. INDICATION(S) FOR USE
#1) SUGAR AND CIRCULATION (Blood glucose abnormal)

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

19. THERAPY DURATION
#1) Unknown

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

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

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	Blood glucose abnormal (Blood glucose abnormal)

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-2024A204043
Study ID: PSP-23269
Case References: CR-AstraZeneca-2024A204043

24b. MFR CONTROL NO.
2024A204043

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

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

DATE OF THIS REPORT
16-MAY-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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

Mfr. Control Number: 2024A204043

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
PATIENT TAKES 2 PILLS PER DAY EVERY 12 HOURS OF XIGDUO 10MG/1000 FOR CIRCULATION (OFF-LABEL USE) [Off label use]	DAPAGLIFLOZIN, METFORMIN	No	No	Not Applicable	Not Applicable
Very rapid increase in sugar [Blood glucose increased]	DAPAGLIFLOZIN, METFORMIN	No	No	Not Applicable	Not Related
Increased cholesterol [Blood cholesterol increased]	DAPAGLIFLOZIN, METFORMIN	No	No	Not Applicable	Related

Case Description: A solicited report has been received from a consumer in Patient Support Program, concerning a male patient born in 1981.

No medical history was reported and concomitant products were reported.

The patient started treatment with Dapagliflozin, Metformin (dapagliflozin, metformin) 10 milligram q12h, Oral use, on an unknown date for sugar and circulation.

On an unknown date, the patient experienced patient takes 2 pills per day every 12 hours of xigduo 10mg/1000 for circulation (off-label use) (preferred term: Off label use), patient has been decompensated (preferred term: Diabetic metabolic decompensation), schizophrenia (preferred term: Schizophrenia), increased cholesterol (preferred term: Blood cholesterol increased), very rapid increase in sugar (preferred term: Blood glucose increased) and cerebral palsy (preferred term: Cerebral palsy).

The report described off-label use for Dapagliflozin, Metformin. The reported term was patient takes 2 pills per day every 12 hours of xigduo 10mg/1000 for circulation (off-label use) (preferred term: Off label use).

The dose of Dapagliflozin, Metformin was not changed.

The outcome of the events of cerebral palsy, increased cholesterol, patient has been decompensated, patient takes 2 pills per day every 12 hours of xigduo 10mg/1000 for circulation (off-label use), schizophrenia and very rapid increase in sugar was unknown.

The company physician considered the events of cerebral palsy, patient has been decompensated and schizophrenia were serious due to medically significant criterion.

The reporter considered the events of increased cholesterol, patient takes 2 pills per day every 12 hours of xigduo 10mg/1000 for circulation (off-label use) and very rapid increase in sugar were non-serious.

The company physician did not consider that there was a reasonable possibility of a causal relationship between Dapagliflozin, Metformin and the following events: patient has been decompensated and very rapid increase in sugar. The company physician considered that there was a reasonable possibility of a causal relationship between Dapagliflozin, Metformin and the following events: cerebral palsy, increased cholesterol and schizophrenia.

Summary of follow-up information received by AstraZeneca on 12-MAY-2025 received via Patient Support Program from consumer: report type updated from NIS to patient support program, Study drug added, New events of Cerebral palsy, Cholesterol blood increased, Schizophrenia, Patient has been decompensated, Very rapid increase in sugar added, Case became valid, Invalid case classification removed, Narrative updated.

Company Clinical Comment: Schizophrenia and Cerebral palsy are not listed in the company core data sheet of dapagliflozin, metformin. Due to limited information on circumstances leading to event, clinical course, treatment provided, action taken, risk factors, concomitant medication, complete etiologic and diagnostic workup the evaluation did not find evidence to exclude a causal relationship between event and suspect drug

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Blood glucose Increased		
2		Blood glucose increased increased		