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	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
Patient indicates that while taking the medication Xigduo 10mg/1000mg her sugar dropped significantly. [Blood glucose decreased]	DAPAGLIFLOZIN, METFORMIN	No	No	Related	Related
Patient comments that she consumed 2 daily doses of Xigduo 10mg/1000mg (off-label use) [Off label use]	DAPAGLIFLOZIN, METFORMIN	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) DAPAGLIFLOZIN, METFORMIN (DAPAGLIFLOZIN, METFORMIN) Tablet

(Continued on Additional Information Page)

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

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

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) 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	Indication	Diabetes (Diabetes mellitus)
13-JAN-2025 to Unknown	Procedure	Surgery (Surgery)

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-202504CAM004778CR
Study ID: PSP-23269
Case References: CR-AstraZeneca-CH-00843975A

24b. MFR CONTROL NO.
202504CAM004778CR

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

NAME AND ADDRESS WITHHELD.

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

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

DATE OF THIS REPORT
30-MAY-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

Mfr. Control Number: 202504CAM004778CR

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 patient born in 1950.

No medical history was reported. Patient was hospitalised for unspecified surgery.

No concomitant products were reported.

The patient started treatment with Dapagliflozin, Metformin (dapagliflozin, metformin) 10 milligram bid, Oral use, on an unknown date for diabetes. On 13-Jan-2025 dose was reduced to 5 milligram as her sugar dropped significantly and the patient had to undergo an operation.

On an unknown date, the patient experienced patient indicates that while taking the medication xigduo 10mg/1000mg her sugar dropped significantly. (preferred term: Blood glucose decreased) and patient comments that she consumed 2 daily doses of xigduo 10mg/1000mg (off-label use) (preferred term: Off label use).

The report described off-label use for Dapagliflozin, Metformin. The reported term was patient comments that she consumed 2 daily doses of xigduo 10mg/1000mg (off-label use).

The dose of Dapagliflozin, Metformin (dapagliflozin, metformin) was reduced.

The patient recovered from the event(s) patient indicates that while taking the medication xigduo 10mg/1000mg her sugar dropped significantly. on an unspecified date. The outcome of the event(s) of patient comments that she consumed 2 daily doses of xigduo 10mg/1000mg (off-label use) was unknown.

The events were considered non-serious.

The reporter did not assess causality for patient comments that she consumed 2 daily doses of xigduo 10mg/1000mg (off-label use).
The reporter considered that there was a reasonable possibility of a causal relationship between Dapagliflozin, Metformin and the following event(s): patient indicates that while taking the medication xigduo 10mg/1000mg her sugar dropped significantly..
The company physician considered that there was a reasonable possibility of a causal relationship between Dapagliflozin, Metformin and the following event(s): patient indicates that while taking the medication xigduo 10mg/1000mg her sugar dropped significantly..

Laboratory values are available.

Summary of follow up information received by AstraZeneca on 23-MAY-2025 from Consumer via Patient Support Program.
Patient indicates that she was hospitalized & Patient indicates that she had surgery while on treatment with Dapagliflozin, Metformin was added. Consent to contact the reporter was updated to no. Narrative updated.
Correction performed on 28-May-2025: Action taken with suspect drug updated to dose reduced.

Case received without translated source documents. Case was processed based on the available populated data and the AOSE comments by selection Albanian language to access the local narrative in English.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Blood glucose decreased		

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) DAPAGLIFLOZIN, METFORMIN (DAPAGLIFLOZIN, METFORMIN) Tablet; Regimen #2	5 milligram; Oral use	Diabetes (Diabetes mellitus)	13-JAN-2025 / Ongoing; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown	Procedure	Hospitalisation (Hospitalisation);