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	GUATEMALA		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
CHANGES IN SUGAR LEVELS. [Blood glucose fluctuation]	FORXIGA	No	No	Related	Related
Forxiga every 2 days (misuse) [Intentional product misuse]	FORXIGA	No	No	Related	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) FORXIGA (DAPAGLIFLOZIN) Film-coated tablet {Lot # WH134; Exp.Dt. OCT-2026}

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

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

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

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	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 #: GT-ASTRAZENECA-202508CAM019530GT
Study ID: PSP-23269
Case References: GT-AstraZeneca-CH-00937376A

24b. MFR CONTROL NO.
202508CAM019530GT

24c. DATE RECEIVED BY MANUFACTURER
25-AUG-2025

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

DATE OF THIS REPORT
27-AUG-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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

NAME AND ADDRESS WITHHELD.

Mfr. Control Number: 202508CAM019530GT

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 1983.

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Forxiga (dapagliflozin) (batch number(s) WH134) (expiration date(s) OCT-2026) 10 milligram qod, Oral use, on an unknown date for diabetes.

On an unknown date, the patient experienced forxiga every 2 days (misuse) (preferred term: Intentional product misuse) and changes in sugar levels. (preferred term: Blood glucose fluctuation).

The dose of Forxiga (dapagliflozin) was not changed.

The patient recovered from the event(s) changes in sugar levels. on an unspecified date. The outcome of the event(s) of forxiga every 2 days (misuse) was unknown.

The events were considered non-serious.

The reporter considered that there was a reasonable possibility of a causal relationship between Forxiga and the following event(s): changes in sugar levels. and forxiga every 2 days (misuse).
The company physician considered that there was a reasonable possibility of a causal relationship between Forxiga and the following event(s): changes in sugar levels..

Laboratory values are available.

13. Lab Data

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