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		65 Years	Female	Unk	25	JUL	2025

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
HIGH SUGAR. [Blood glucose increased]	FORXIGA	Yes	No	Related	Not 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) FORXIGA (DAPAGLIFLOZIN) Film-coated tablet {Lot # WH0134; Exp.Dt. OCT-2026}

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)

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

18. THERAPY DATES(from/to)
#1) 16-JUL-2025 / 28-JUL-2025

19. THERAPY DURATION
#1) 13 days

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 #: CR-ASTRAZENECA-202508CAM002557CR
Study ID: PSP-23269
Case References: CR-AstraZeneca-CH-00925206A

24b. MFR CONTROL NO.
202508CAM002557CR

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

NAME AND ADDRESS WITHHELD.

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

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

DATE OF THIS REPORT
08-AUG-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 202508CAM002557CR

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Case Description: A solicited report has been received from a consumer in Patient Support Program concerning a female elderly patient born in 1960 (age 65 years).

No medical history was reported. No concomitant products were reported.

The patient started treatment with Forxiga (dapagliflozin) (batch number(s) WH0134) (expiration date(s) OCT-2026) 10 milligram qd, Oral use, on 16-JUL-2025 for diabetes.

On 25-JUL-25, the patient experienced high sugar. (preferred term: Blood glucose increased).
The last dose of FORXIGA prior to onset was taken on 28-JUL-25.

Treatment with Forxiga was discontinued on 28-JUL-2025.

The patient recovered from the event(s) high sugar. on an unspecified date.

The event was considered serious (Medically Significant).

The reporter considered that there was a reasonable possibility of a causal relationship between Forxiga and the following event(s): high sugar..
The company physician did not consider that there was a reasonable possibility of a causal relationship between Forxiga and the following event(s): high sugar..

Laboratory values are available.

Company Clinical Comment: Blood glucose increased is not listed in the company core data sheet of dapagliflozin. Underlying diabetes mellitus along with age of patient could be contributory to the event. Due to limited information on relevant medical history, circumstances surrounding the event, aetiological and diagnostic workup, therapy compliance, concurrent diseases, concomitant medications, risk factors, family history, the evaluation did not find evidence to suggest a causal relationship between the event and the suspect drug.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Blood glucose 123		