CIOMS FORM

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	Male	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
Increased blood sugar levels [Blood glucose increased]	FORXIGA	No	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) FORXIGA (DAPAGLIFLOZIN) Film-coated tablet {Lot # Unknown}

15. DAILY DOSE(S)
#1) Unknown

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

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

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

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)
#1) Metformin (Metformin hydrochloride) ; Unknown

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)

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-202508CAM019468CR
Study ID: PSP-23269
Case References: CR-AstraZeneca-CH-00937402A

24b. MFR CONTROL NO.
202508CAM019468CR

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.
NAME AND ADDRESS WITHHELD.

Mfr. Control Number: 202508CAM019468CR

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Case Description: A solicited report has been received from a correspondence contact in Patient Support Program. The report concerns a male patient born in 1942.

No medical history was reported.

Concomitant medication included Metformin.

The patient started treatment with Forxiga (dapagliflozin) (batch number(s) Unknown) 10 milligram qd, Oral use, on an unknown date for diabetes.

On an unknown date, the patient experienced increased blood sugar levels (preferred term: Blood glucose increased).

At the time of reporting, the event increased blood sugar levels was improving.

The event was considered non-serious.

The reporter did not assess causality for increased blood sugar levels.
The company physician considered that there was a reasonable possibility of a causal relationship between Forxiga and the following event(s): increased blood sugar levels.

Laboratory values are available.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Blood glucose		
2		X-ray 10/1000		