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		78 Years	Female	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 is broken due to fall [Lower limb fracture]	FORXIGA	Yes	No	Not Related	Not Related
fall [Fall]	FORXIGA	Yes	No	Not 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 # IP0057; Exp.Dt. OCT-2026}

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

15. DAILY DOSE(S)
#1) Unknown

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	Current Condition	Diabetes (Diabetes mellitus)
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-202503CAM021457CR
Study ID: PSP-23269
Case References: CR-AstraZeneca-CH-00835086A

24b. MFR CONTROL NO.
202503CAM021457CR

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

NAME AND ADDRESS WITHHELD.

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

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

DATE OF THIS REPORT
09-JUL-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

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 elderly patient born in 1946 (age 78 years).

The patient’s past and current medical history included diabetes (ongoing).

No concomitant products were reported.

The patient started treatment with Forxiga (dapagliflozin) (batch number(s) IP0057) (expiration date(s) OCT-2026) 10 milligram qd, Oral use, on an unknown date for diabetes.

On an unknown date, the patient experienced patient is broken due to fall (preferred term: Lower limb fracture) and fall (preferred term: Fall).

It is unknown if any action was taken with Forxiga (dapagliflozin).

At the time of reporting, the event fall and patient is broken due to fall was improving.

The events were considered serious (Medically Significant).

The reporter did not consider that there was a reasonable possibility of a causal relationship between Forxiga and the following event (s): fall and patient is broken due to fall.

The company physician did not consider that there was a reasonable possibility of a causal relationship between Forxiga and the following event(s): fall and patient is broken due to fall.

Corrected report on 09-Jul-2025: Reporter causality updated from not applicable to not related. Event patient is broken due to fall recoded. Narrative amended.