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)

Other Serious Criteria: Medically Significant

Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)	Product	Serious	Listed	Reporter Causality	Company Causality
Hypotension [Hypotension]	FORXIGA	Yes	No	Related	Related
Fainting [Syncope]	FORXIGA	Yes	No	Related	Not Related
Dizziness [Dizziness]	FORXIGA	No	No	Related	Related
Patient takes the medication Forxiga for hyperproteinemia (off-label) [Off label use]	FORXIGA	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) FORXIGA (DAPAGLIFLOZIN) Film-coated tablet

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

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

17. INDICATION(S) FOR USE
#1) HYPERPROTEINEMIA (Hyperproteinaemia)

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)

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	Hyperproteinaemia (Hyperproteinaemia)
Unknown	Indication	Hyperproteinemia (Hyperproteinaemia)

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-202505CAM024252CR
Study ID: PSP-23269
Case References: CR-AstraZeneca-CH-00879799A

24b. MFR CONTROL NO.
202505CAM024252CR

24c. DATE RECEIVED BY MANUFACTURER
28-MAY-2025

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

DATE OF THIS REPORT
29-MAY-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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

NAME AND ADDRESS WITHHELD.

Mfr. Control Number: 202505CAM024252CR

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)	Product	Serious	Listed	Reporter Causality	Company Causality
Pressure [Blood pressure abnormal]	FORXIGA	No	No	Not Applicable	Related

Case Description: A solicited report has been received from a consumer in Patient Support Program concerning a male patient born in 1949.

No medical history was reported, and no concomitant products were reported.

On an unknown date, the patient started treatment with Forxiga (dapagliflozin) 10 milligram qd, Oral use for hyperproteinemia.

On an unknown date, the patient experienced hypotension (preferred term: Hypotension), pressure (preferred term: Blood pressure abnormal), patient takes the medication forxiga for hyperproteinemia (off-label) (preferred term: Off label use), dizziness (preferred term: Dizziness) and fainting (preferred term: Syncope).

The report described off-label use for Forxiga. The reported term was patient takes the medication forxiga for hyperproteinemia (off-label) (preferred term: Off label use).

The patient recovered from the event(s) dizziness, fainting and hypotension on an unspecified date. The outcome of the event(s) of patient takes the medication forxiga for hyperproteinemia (off-label) and pressure was unknown.

The following event(s) were considered serious due to life-threatening:hypotension. The following event(s) were considered serious due to medically significant:fainting.

The following events were considered non-serious:dizziness, patient takes the medication forxiga for hyperproteinemia (off-label) and pressure.

The reporter did not assess causality for patient takes the medication forxiga for hyperproteinemia (off-label) and pressure.

The reporter considered that there was a reasonable possibility of a causal relationship between Forxiga and the following event(s): dizziness, fainting and hypotension.

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

The company physician considered that there was a reasonable possibility of a causal relationship between Forxiga and the following event(s): dizziness, hypotension and pressure.

Laboratory values are available.

Company Clinical Comment: Hypotension is not listed in the Core Data Sheet for dapagliflozin. Underlying Hyperproteinaemia could be confounding factor for the event. Due to limited information on start date of suspect, final outcome of the event, concomitant medications, concomitant conditions, risk factors, medical history, relevant family history, circumstances leading to event, treatment given detailed etiological and diagnostic work up including baseline reports if any, the evaluation did not find evidence to exclude a reasonable possibility of a causal relationship between the event and the suspect drug.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Hypertension	high millimetre of mercury	