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		87 Years	Female	Unk		APR	2025

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
Heart failure [Cardiac failure]	FORXIGA	Yes	No	Not Related	Not Related
ALLERGIES ON HER FACE (NOSE, EYES, EYELIDS), HEAD AND THROAT [Hypersensitivity]	FORXIGA	No	No	Not Related	Not Related
Sugar in the kidney [Renal disorder]	FORXIGA	No	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 # WL0172; Exp.Dt. APR-2027}

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) (Not Coded)

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

18. THERAPY DATES(from/to)
#1) 2019 / 11-JUN-2025

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	Historical Condition	Caregiver (Caregiver)
Unknown	Procedure	Pacemaker insertion (cardiac) (Cardiac pacemaker insertion)

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-202507CAM017270CR
Study ID: PSP-23269
Case References: CR-AstraZeneca-CH-00915377A

24b. MFR CONTROL NO.
202507CAM017270CR

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

NAME AND ADDRESS WITHHELD.

24c. DATE RECEIVED BY MANUFACTURER
21-JUL-2025

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

DATE OF THIS REPORT
23-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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 1938 (age 87 years).

The patient’s past and current medical history included caregiver (dates not reported).

No concomitant products were reported.

The patient started treatment with Forxiga (dapagliflozin) (batch number(s) WL0172) (expiration date(s) APR-2027) 10 milligram qd, Oral use, during 2019.

During 15-APR-25, the patient experienced allergies on her face (nose, eyes, eyelids), head and throat (preferred term: Hypersensitivity). On 11-JUN-25, the patient experienced sugar in the kidney (preferred term: Renal disorder). On an unknown date, the patient experienced heart failure (preferred term: Cardiac failure).
The last dose of FORXIGA prior to onset was taken on 11-JUN-25.

The dose of Forxiga (dapagliflozin) was not changed.

The patient recovered from the event(s) heart failure on an unspecified date. At the time of reporting, the event allergies on her face (nose, eyes, eyelids), head and throat and sugar in the kidney was ongoing.

The following event(s) were considered serious due to hospitalized:heart failure.

The following events were considered non-serious:allergies on her face (nose, eyes, eyelids), head and throat and sugar in the kidney.

The reporter did not consider that there was a reasonable possibility of a causal relationship between Forxiga and the following event (s): allergies on her face (nose, eyes, eyelids), head and throat, heart failure and sugar in the kidney.
The company physician did not consider that there was a reasonable possibility of a causal relationship between Forxiga and the following event(s): allergies on her face (nose, eyes, eyelids), head and throat, heart failure and sugar in the kidney.