SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET		
		Day	Month	Year				Day	Month	Year
PRIVACY	GUATEMALA		PRIVACY		Unk	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
calor [Feeling hot]	FORXIGA	No	No	Not Related	Not Related
Sofoco [Asphyxia]	FORXIGA	Yes	No	Not Related	Not Related
Sweating [Hyperhidrosis]	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 # TTP0057; 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) Ongoing

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	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 #: GT-ASTRAZENECA-202505CAM017732GT
Study ID: PSP-23269
Case References: GT-AstraZeneca-CH-00875325A

24b. MFR CONTROL NO.
202505CAM017732GT

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

NAME AND ADDRESS WITHHELD.

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

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

DATE OF THIS REPORT
27-MAY-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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
HOT FLUSH [Hot flush]	FORXIGA	No	No	Not Applicable	Not Related

Case Description: A solicited report has been received from a consumer in Patient Support Program. The report concerns a female patient born in 1966.

No medical history and concomitant products were reported.

The patient started treatment with Forxiga (dapagliflozin) (batch number(s) TTP0057) (expiration date(s) OCT-2026) 10 milligram qd, Oral use, on an unknown date for diabetes.

On an unknown date, the patient experienced hot flush (preferred term: Hot flush), sweating (preferred term: Hyperhidrosis), sofoco (preferred term: Asphyxia) and calor (preferred term: Feeling hot).

The dose of Forxiga was not changed.

The patient recovered from the event(s) calor, sofoco and sweating on an unspecified date. The outcome of the event(s) of hot flush was unknown.

The following event(s) were considered serious due to medically significant: sofoco.

The following events were considered non-serious: calor, hot flush and sweating.

The reporter did not assess causality for hot flush.The reporter did not consider that there was a reasonable possibility of a causal relationship between Forxiga and the following event(s): calor, sofoco and sweating.

The company physician did not consider that there was a reasonable possibility of a causal relationship between Forxiga and the following event(s): calor, hot flush, sofoco and sweating.